The Pharmaceutical Market in Greece
FACTS AND FIGURES 2018

FOUNDATION
FOR ECONOMIC
& INDUSTRIAL
RESEARCH

SfEE
HELLENIC ASSOCIATION
OF PHARMACEUTICAL COMPANIES

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ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

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The report “The Pharmaceutical Market in Greece: Facts & Figures 2018” was produced by Health Economics Observatory research staff of IOBE with the cooperation of SfEE’s Data Monitoring Committee.

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FOREWORD -ACKNOWLEDGMENTS

«The Pharmaceutical Market in Greece: Facts & Figures 2018»

It is with great pleasure to preface the renewed annual edition 'The Pharmaceutical Market in Greece: Facts & Figures 2018', produced by research staff of IOBE in collaboration with SfEE's Data Monitoring Committee.

As it has been established during the past years from our association, this report intends to provide the most comprehensive overview of key facts and data of the pharmaceutical market in Greece, in order to inform both our members and other stakeholders in the broader health sector.

More specifically, this year's edition covers the most important social and economic changes from the long recessionary period in our country, and records the impact of fiscal adjustment on health and specifically on pharmaceutical sector, through comparison with other European Union countries, and with Southern countries implemented similar economic adjustment programs.

This edition attempted to include all data available until the end of 2018, in order to present an updated profile of the pharmaceutical market and the main changes that occurred.

The country after the completion of the Fiscal Adjustment programs, entered into a new era in which strategic planning and vision to shape a national health strategy are required, in this context, this report aims to demonstrate the added value of pharmaceutical sector for the Greek economy

We would like to thank the IOBE research staff and the members of SfEE Data Monitoring Committee

Dimitris Anagnostakis

President of the Data Monitoring Committee

Olympios Papadimitriou

President of SfEE

EXECUTIVE SUMMARY

Based on the latest available data from EL.STAT., Gross Domestic Product (GDP) of the Greek economy amounted at €187 bil. in 2017, increased by 1.5% compared to 2016. For 2018, GDP growth rate is projected to increase 1.9%, with marginal acceleration projected for 2019-2020.In any case, GDP could reach €200 bil. for the first time since 2012.

These **demographic trends** also directly affect the population's dependency ratio. In Greece nearly half of the population is dependent on the other half, and its proportion is expected to growth, signaling increased pressure on the social security system. In 2018, Greece's dependency ratio reaches 53%, meaning that **for every 2 active people there is 1 inactive,** close to EU28 average (54%) and the average of Southern countries (55%).Over time, there has been a strong rise in the number of deaths in Greece due to circulatory system diseases in 2015 accounted for 38.3% of total deaths, while the number of deaths due to neoplasms is continuously increasing and estimated at 25.0% of total deaths.

Total health expenditure decreased by -30.9% during the period 2010-2017 (+ 0.9% in Southern countries, +10.0% in the EU), amounted at €14.9 bil. in 2017 (8, 4% of GDP). **Public health expenditure** decreased by -38.2% (-4.8% in Southern countries, + 14.0% in the EU) over the same period, amounted at €9.1 bil. in 2017 (5.1 % of GDP). The decline in public health expenditure has resulted in a shift in health spending to the private sector, with **private health expenditure** reaching 39% in 2016 (28% in Southern countries, 20% in the EU).

However, the needs of the population for health care are affected, amongst others, by demographic trends: **life expectancy in Greece is high** (81.5 years higher than EU average 81.0 years in 2016), steady **reduction of the population** (births - deaths) by -36,000 people (2017), and **increased ageing population** (over 65) from 21.9% of the total population in 2017 rising to 36.5% in 2050.

From the above, the **growing demand for health care,** thus for public funding on health care services and pharmaceuticals is documented, with further increase in the private expenditure considered unsustainable in an environment of long-term unemployment and significant decline of national income.

With regards to the pharmaceutical expenditure, which is a small part of total health expenditure (~20%), total outpatient pharmaceutical expenditure in Greece estimated at €3.6 bil. in 2018, (€1,945 bil. is public pharmaceutical expenditure). While total out-of-hospital pharmaceutical expenditure remains relatively stable over the period 2012-2018, **public outpatient pharmaceutical expenditure decreased by -62% the same period.** At the same time the weight shifted towards private sector, with **industry's contribution**, through flat mandatory returns and discounts (rebate and clawback). As far as public hospital pharmaceutical expenditure is concerned during the period 2012-2015 amounted to €760 mil. From 2016 onwards, with the introduction of closed budget, it was significantly reduced by -30%, resulting in the contribution of pharmaceutical industry with €436 mil. in 2018.

The significant reduction in the public sector's contribution to pharmaceutical spending has resulted in a shift to the private sector where for 2018 **patient participation** in outpatient pharmaceutical expenditure reaches around €625 mil. and **industry** in €990 mil., while in hospital pharmaceutical expenditure the participation of the industry reaches to €436 mil. As a result, the industry for 2018 with rebate and clawback mechanisms has reached the needs of Greek patients for pharmaceutical coverage with 1 out of 3 medicines (30%) in out-patient and 1 in 2 medicines (45 %) at hospital level.

Despite the significant impact of fiscal adjustment on public funding, **the pharmaceutical industry remains a pillar for investment** in Greece with Research and Development (R&D) expenditure close to 8% of total R&D expenditure in Greece (2015) and 2,506 clinical studies independent of phase and stage conducted until 2018 (1,434 completed). Production of pharmaceutical products in Greece was estimated at €954 mil., with Gross Value Added (ex-factory) at €668 mil. (3.0% of the manufacturing). Employment in the manufacturing of pharmaceutical products in Greece was estimated at 14.4 thousand people in 2017, with 60.5% of them with university education, compared to 35.7% of the total economy and 22.7% of the total manufacturing.

Imports and exports of medicinal products amounted to €2.8 bil. and €1.4 bil., respectively in 2018. Lastly, exports accounted for 4.3% of total Greek exports in 2018.

CHAPTER 1

KEY STATISTICS OF GREEK PHARMACEUTICAL MARKET

DEMOGRAPHIC FACTORS

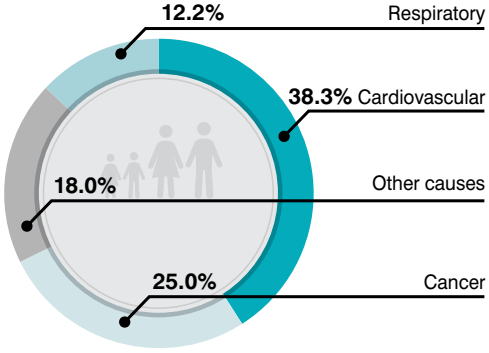
"Life expectancy is high, steady reduction of the population (births-deaths) and increased ageing population"

	Greece	Southern countries	EU
Life expectancy (years) 2016	81.5	83.2	81.0
Births-Deaths (thousand persons) 2017	-35,948	-245,286	-190,871
Share of population > 65 years (%) 2020	22.6%	21.8%	20.4%

SOURCE: OECD, Health Statistics 2018, Southern countries (Italy, Spain, Portugal), data processing IOBE, Natural change is defined as the change due only to the difference in births - deaths without taking into account immigration. The number of births does not include stillbirths, which in 2017 amounted to 363. Eurostat, Population Projections, 2018, data processing IOBE, not included the possible legalization of migration from 2015 onwards

Causes of death (% total deaths 2015)

"Circulatory system diseases are responsible for 38.3% of total deaths"



SOURCE : EL.STAT., 2018, Pursuant to the 9th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-10) the following are included: cases when it is stated that an investigation by a medical or legal authority has not determined whether the injuries are accidental, suicidal or homicidal; deaths caused by injuries inflicted by law-enforcing agents (including military) on duty in the course of attempting to enforce the Law; deaths caused by injuries during war operations. Other causes: Diseases of the digestive system, Diseases of the genitourinary system, Diseases of the nervous system and sense organs, En docrine and metabolic diseases, nutrional deficiencies and immune disorders

SOCIAL FACTORS

"The high unemployment rate, more profound on young people - almost half out of the labour market - composing the most productive age group, resulting in brain drain"

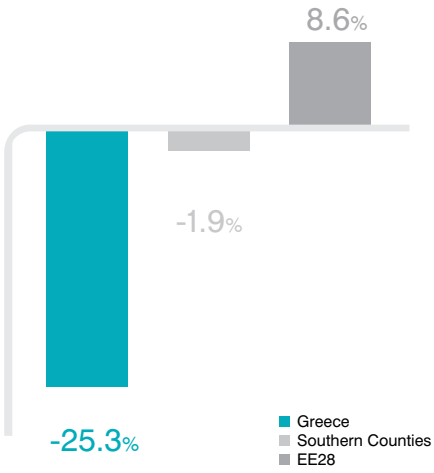
		Greece	Southern countries	EU
Unemployment (%) 2017	Population	21.5%	12.9%	7.6%
	15-24 years	47.3%	39.6%	18.7%
Poverty Risk (%)2017		34.8%	27.3%	22.5%

SOURCE: Eurostat, 2019, European Commission, Winter, 2019 Economic Forecast, data processing IOBE. Southern countries (Italy, Spain, Portugal). Percentage of people at risk of poverty: percentage of people with disposable income equivalents below 60% of the national median income. Median income is the income above which is the 50% of the population

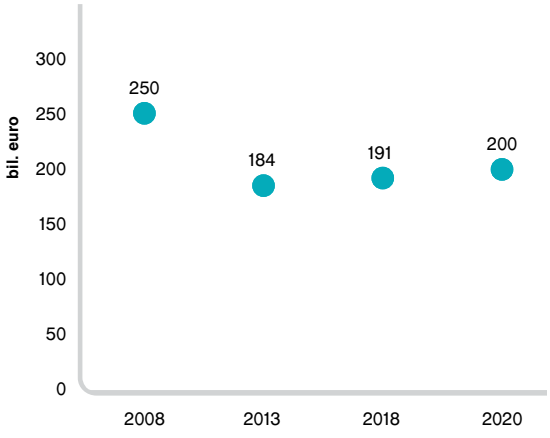
ECONOMIC FACTORS

"For 2018 growth rate increased, with a slight recovery for 2019-2020"

Cumulative GDP change
(2017 with baseline 2007)



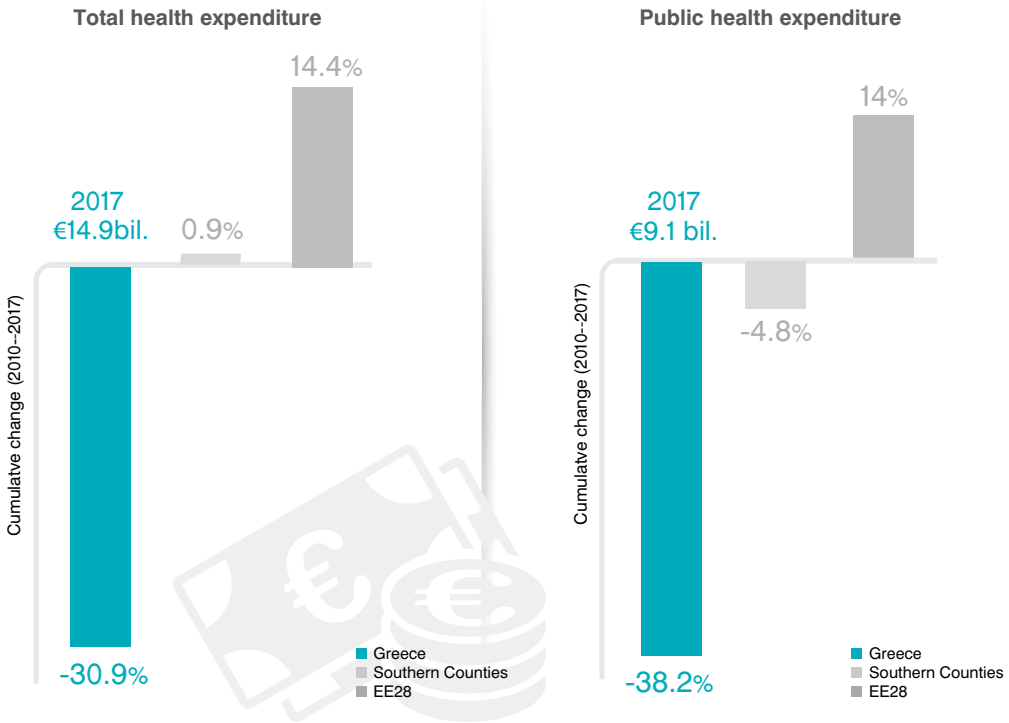
Evolution of GDP in Greece (bil. €) 2008-2020



SOURCE: Eurostat 2019, AMECO , European Commission, Winter 2019 Economic Forecast, (February 2019), GDP Chain linked volumes 2010, data processing IOBE. Southern countries (Italy, Spain, Portugal).

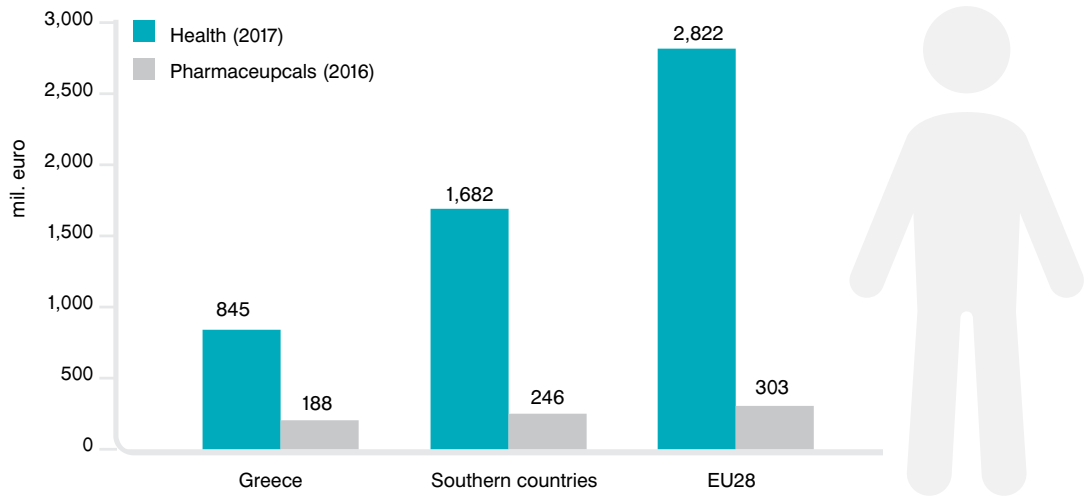
HEALTH AND PHARMACEUTICAL EXPENDITURE

"Total health expenditure decreased by -30.9% in the period 2010-2017, with «the largest decline in public health expenditure by -38.2%, respectively"



SOURCE: System Health Account (SHA) 2016, OECD Health Statistics, 2018, IOBE data processing. Southern Countries (Italy, Spain, Portugal) Percentage changes between 2009 and 2017 have been calculated in the Fixed Price Data ($ 2010 PPS, OECD).

Public per capita health expenditure and pharmaceutical and other medical goods expenditure

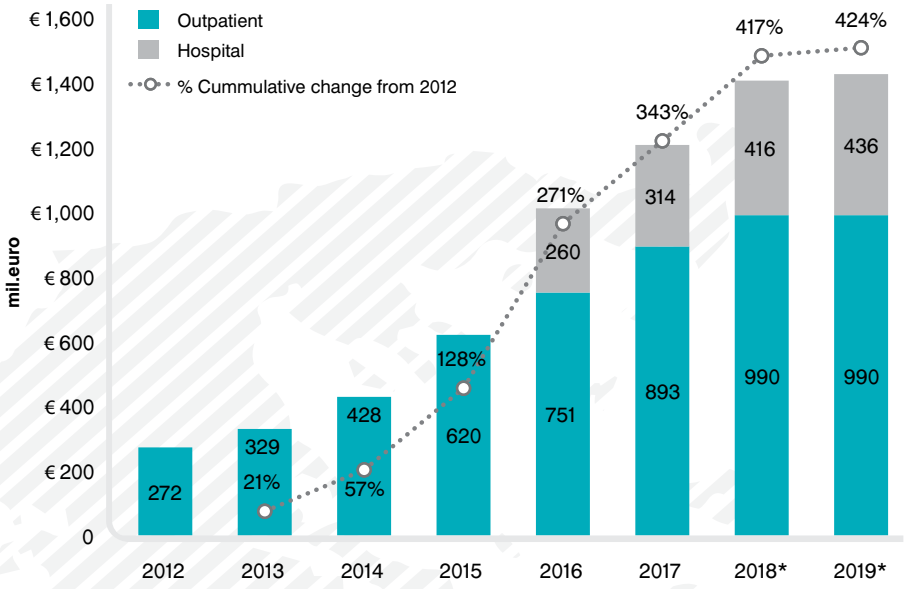


SOURCE: OECD Health Statistics, 2018, data processing IOBE. Southern Countries (Italy, Spain, Portugal).The EU refers to the average of 23 EU countries due to unavailability of data for other countries

THE CONTRIBUTION OF PHARMACEUTICAL INDUSTRY IN THE GREEK HEALTH SYSTEM

"The significant reduction in the public sector's contribution to pharmaceutical expenditure, resulted in a shift towards private sector and the pharmaceutical industry especially. The pharmaceutical industry, through clawback and rebates, covers the needs of patients for pharmaceutical coverage by providing free of charge 1 out of 3 outpatient and 1 out of 2 hospital medicines"

Industry contribution on total pharmaceutical expenditure (clawback and rebates)



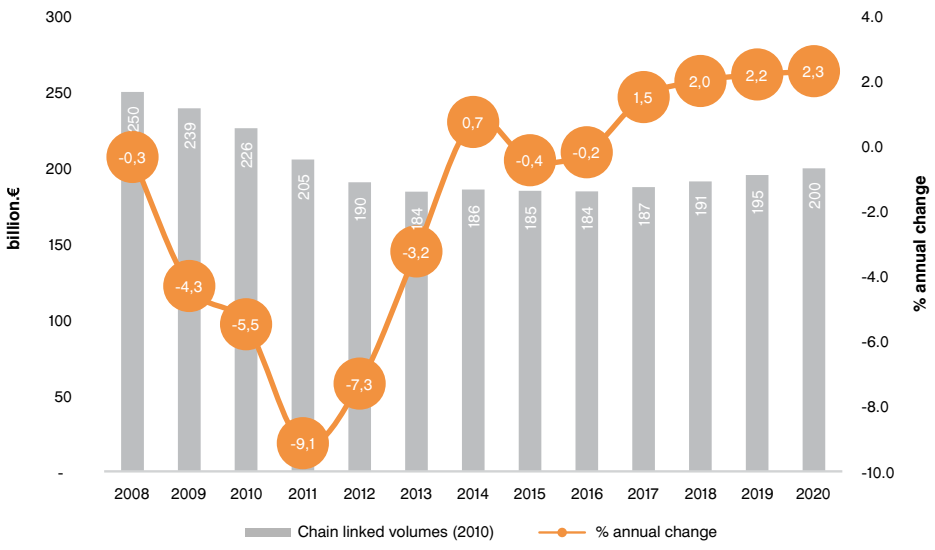
CHAPTER 2

ECONOMIC ENVIRONMENT

2.1 MACROECONOMIC INDICATORS

Gross Domestic Product (GDP) of the Greek economy amounted to €187 bil. in 2017, increased by 1.5% compared to 2016. For 2018, growth rate is projected at 2.0%, with a further strengthening over 2018-2019. The latest estimations of the European Commission (Winter 2019) are revised on better than previous autumn estimates while, the estimation of IOBE places growth at the same levels for 2018, while growth will surpass 2.0%, with significant push from private and public consumption as well investments.

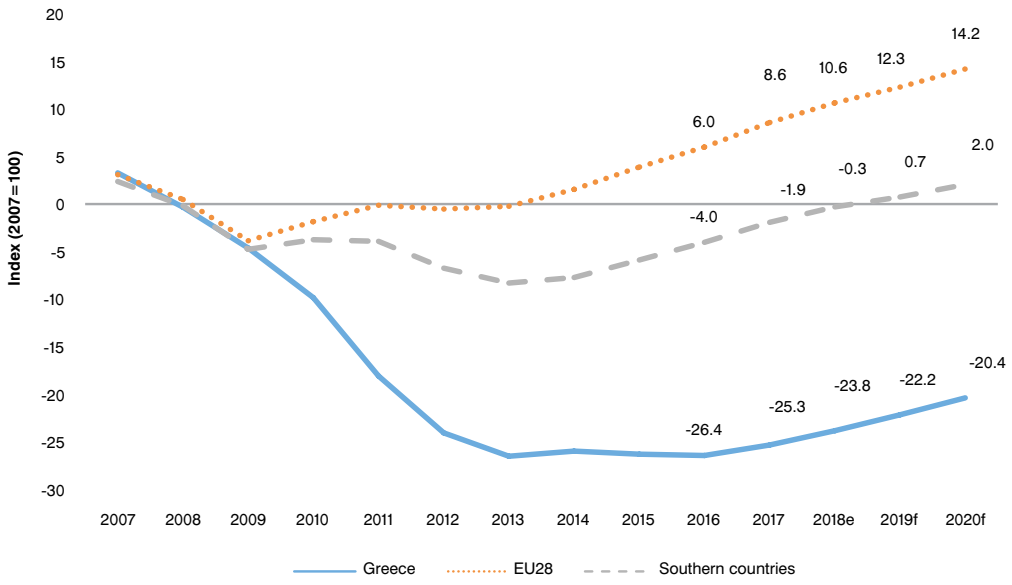
Figure 1: GDP (€) and annual change (%) - Greece



SOURCE: Eurostat, 2019, AMECO, European Commission Winter 2019 Economic Forecast (February 2019), GDP Chain linked volumes 2010, data processing IOBE

The GDP of the Greek economy had a cumulative loss of -26.4% in the period 2007-2016, while in the Southern countries, losses in the same period were down to -4.0%, while in EU 28, increased by 6.0%. It is noted that in the period 2017-2020, if the estimates are verified and projections, Greece will show a cumulative increase in the GDP by 8.2%, versus 7.7% in the EU28 and 6.3% in the Southern countries.

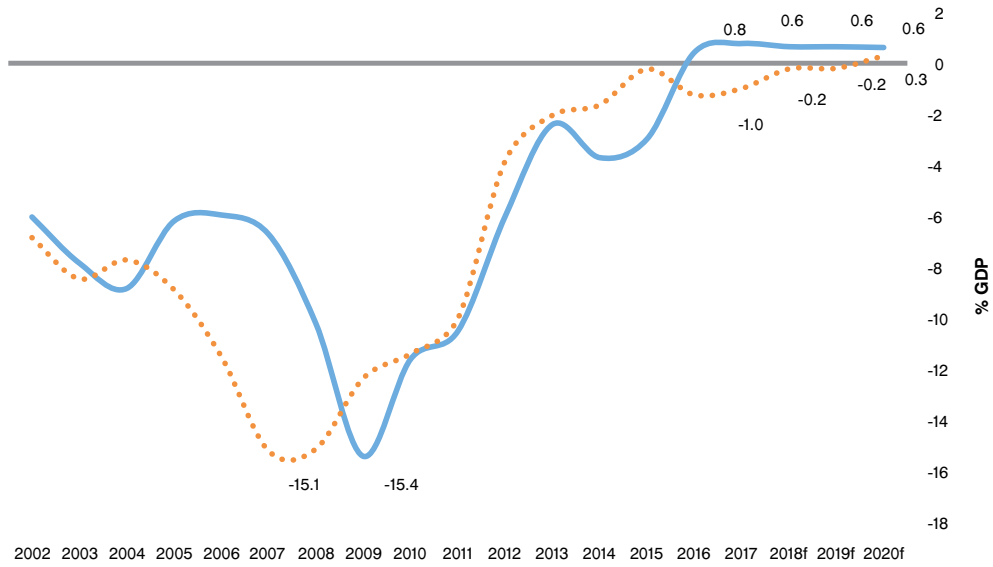
Figure 2: Index of cumulative GDP change (%) Greece-EU28-Southern countries



SOURCE: Eurostat, 2019, AMECO, European Commission, Winter 2019 Economic Forecast (February 2019), GDP Chain linked volumes 2010, data processing IOBE*Southern countries (Italy, Spain, Portugal), e-estimation, f-forecast

The Greek economy has experienced a persistent recession, as a major economic adjustment program was implemented after 2010, with reduced public spending and increased taxation, resulting in a significant decline of GDP. The program corrected the imbalances of the Greek economy, both in the domestic sector (General Government Balance) and in the external sector (Current Account Balance). In particular, the very high deficits of -15.1% in 2008 in the current account balance and -15.4% in 2009 in the general government balance decreased significantly, with the latter indicating a positive sign in 2018 (+0.6 points), while a significant correction was made to the current account balance with a sharp downturn in imports.

Figure 3: General Government Balance & Current Account Balance (% GDP)

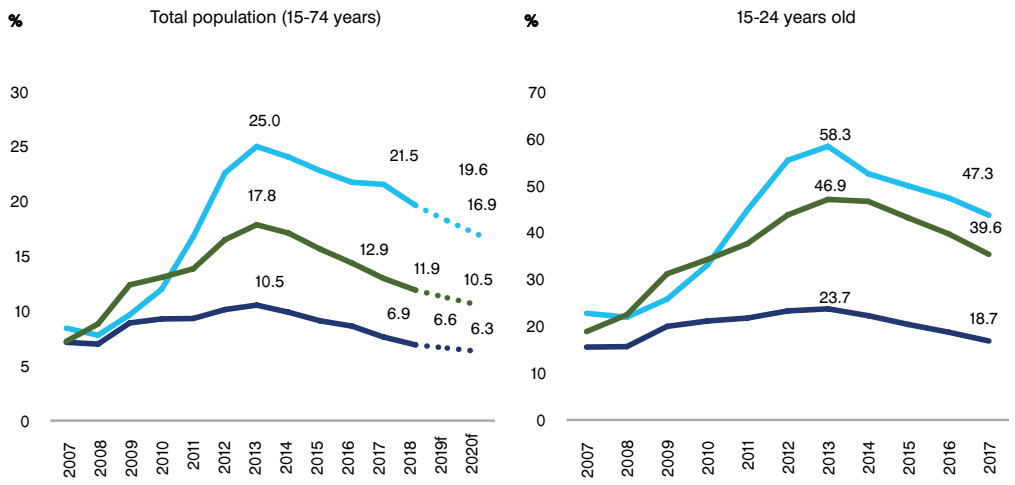


SOURCE: EL.STAT., AMECO, 2018, European Commission Winter 2019 Economic Forecast (February 2019), data processing IOBE. The government budget deficit also includes interest on debt repayment but does not include extraordinary entries in revenues and expenses due to the recapitalization of banks in 2012-2015. The external sector balance is reported in the current account balance and includes the balances of goods and Services, Primary Income (Labour, Entrepreneurship) and Secondary Income (Current Transfers), general government Balance does not include the impact of the support to the financial institutions from all interventions during the financial crisis on the general government deficit.

2.2 SOCIAL ENVIRONMENT

In Greece, the unemployment rate of the general population climbed to a historically high level of 25.0% in 2013, with a gradual improvement to 21.5% in 2017 and further de-escalation in 2018 to 19.6%, still very high for a European country. With lower tension in Southern countries, unemployment rate reached 17.8% in 2013 and fell to 11.9% in 2018, lower than the unemployment rate in EU28. Unemployment among young people aged 15-24, remains very high in Greece, at 47.3% in 2017, compared with 39.6% in the South countries and 18.7% in the EU 28.

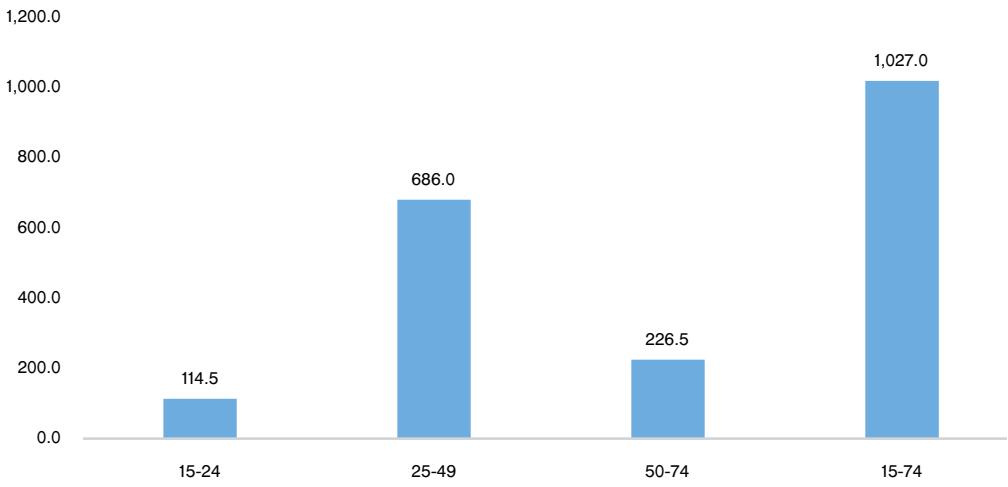
Figure 4: Unemployment rate (% of total population) Greece-EU28-Southern countries



SOURCE: Eurostat, 2018, AMECO 2018, European Commission, Autumn 2018 Economic Forecast, data processing IOBE. Southern countries (Italy, Spain, Portugal), f-forecast

At the same time, in 2017 a high rate of long-term unemployment is recorded at 72.8% of the total unemployed, that is 747 thousand people remain out of the labour market for more than 12 months. The highest unemployment rate is found among young people aged 15-24, while in absolute numbers the largest number of unemployed comes from ages 25-49, the most productive age group, with about 686 thousand people unemployed.

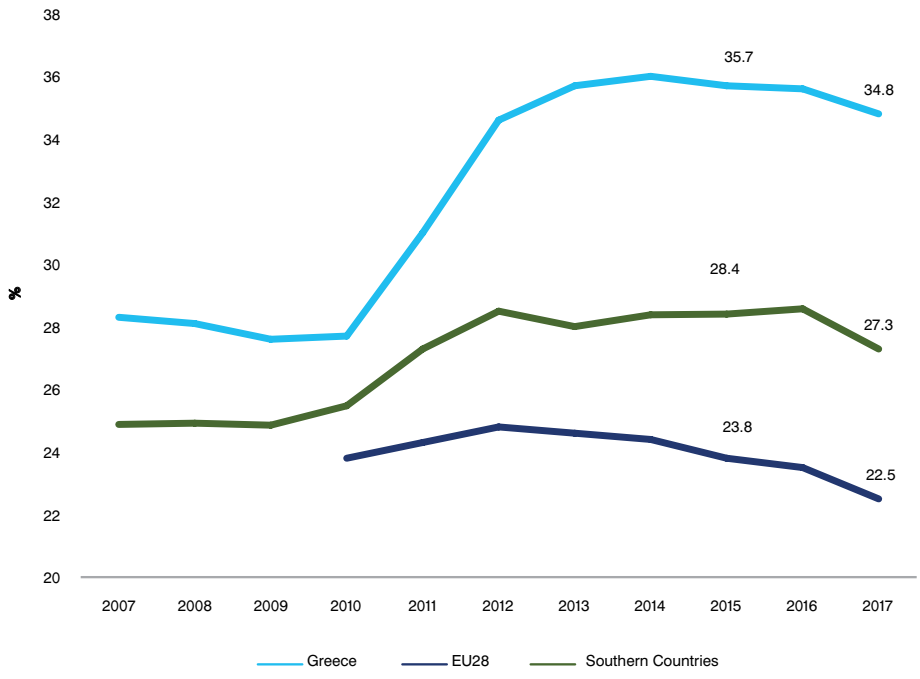
Figure 5: Number of unemployed (thousand people) by age group - Greece (2017)



SOURCE: Eurostat, 2018 (percentages refer to the active population of this age group who are unemployed), data processing IOBE

The decrease in the national income and the significant increase of unemployment led a large part of the population at risk of poverty, ie people with income below 60% of median income. In Greece, the proportion of the population at risk of poverty reached 36% of the total population in 2014, a high figure taking into account that the income threshold has declined significantly in 2014 and slightly narrowed in 2016 and 2017. In Southern countries that implemented similar fiscal adjustment program population at risk of poverty was close to 29%, well below the level of Greece.

Figure 6: Poverty risk (% of total population) Greece-EU28-Southern countries



SOURCE: Eurostat, 2018, data processing IOBE. Percentage of people at poverty risk: percentage of people with disposable income below 60% of the national median income. Median income is the income above which is the 50% of the population. Southern countries (Italy, Spain, Portugal)

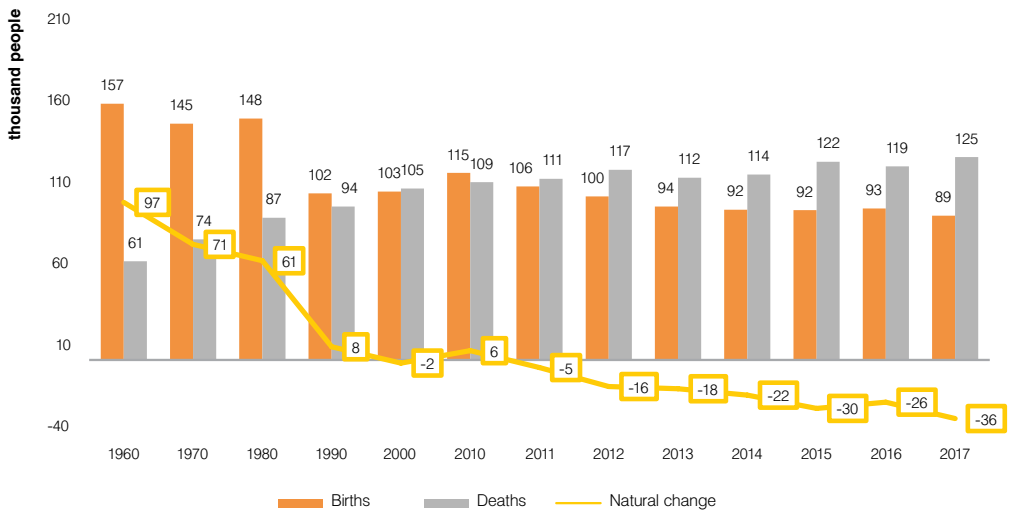
CHAPTER 3

DEMOGRAPHIC TRENDS AND HEALTH PROFILE OF THE POPULATION

3.1 NATURAL POPULATION CHANGE

The number of births in Greece amounted to 89 thousand people in 2017 recording a 4.7% decrease from previous year, while the number of deaths recorded an increase of 4.8%, amounting to 125 thousand people. As such, the natural population change (difference births - deaths) was negatively affected in 2017, resulting in an overall reduction of -36 thousand people in the national population.

Figure 7: Natural change of population (thousand people)-Greece

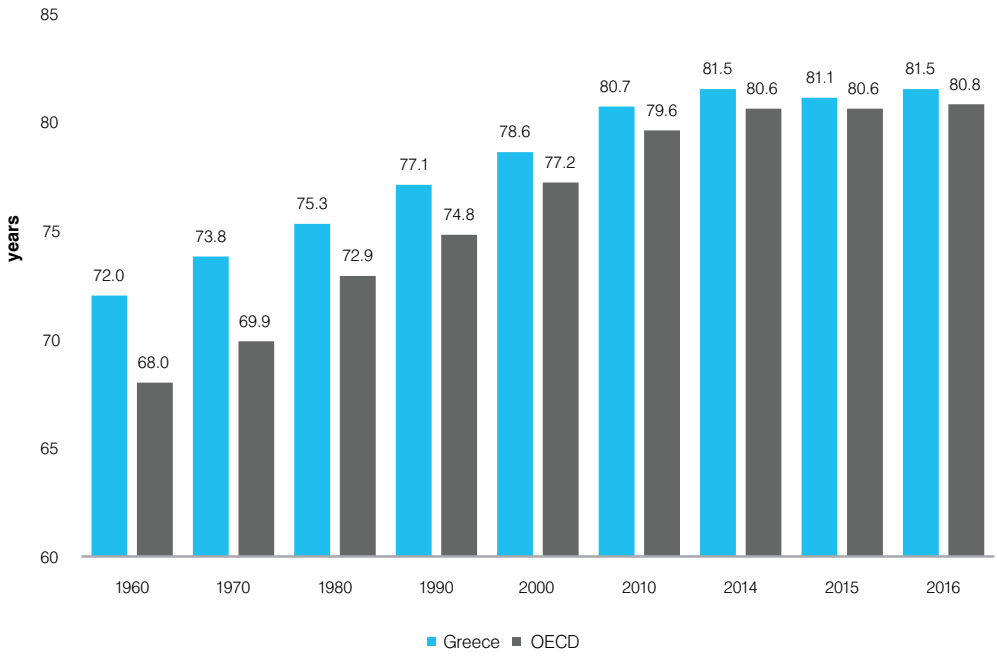


SOURCE: EL. STAT., 2018 *Natural change is defined as the change due only to the difference in births - deaths without taking into account immigration ** The number of births does not include stillbirths, which in 2017 amounted to 363

3.2 LIFE EXPECTANCY

The technological advances, improvement in the provision of healthcare services, contribution of R&D and introduction of innovative new drugs and therapies partially are some of the most important factors explaining the increase of life expectancy. Life expectancy in Greece has increased considerably by 9.5 years during 1960-2016 and it is higher than the average of OECD countries in the same period.

Figure 8: Evolution of life expectancy at birth (years) in Greece-OECD

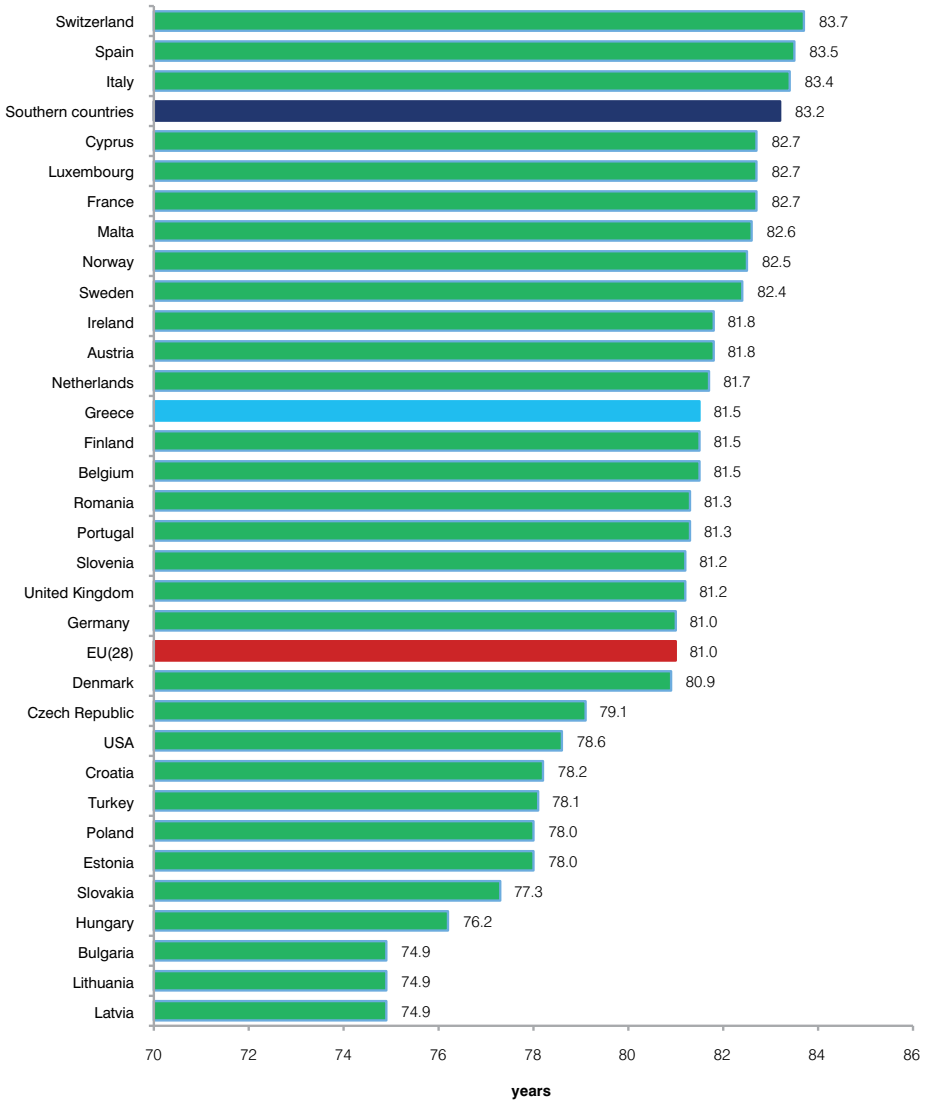


SOURCE: OECD, Health Statistics 2018

3.3 AGEING POPULATION

Life expectancy in Greece reached 81.5 years in 2016, which is higher from EU28 average (81.0 years) and lower than in Southern countries (83.2 years). The highest life expectancy was recorded in Switzerland, Spain, and Italy.

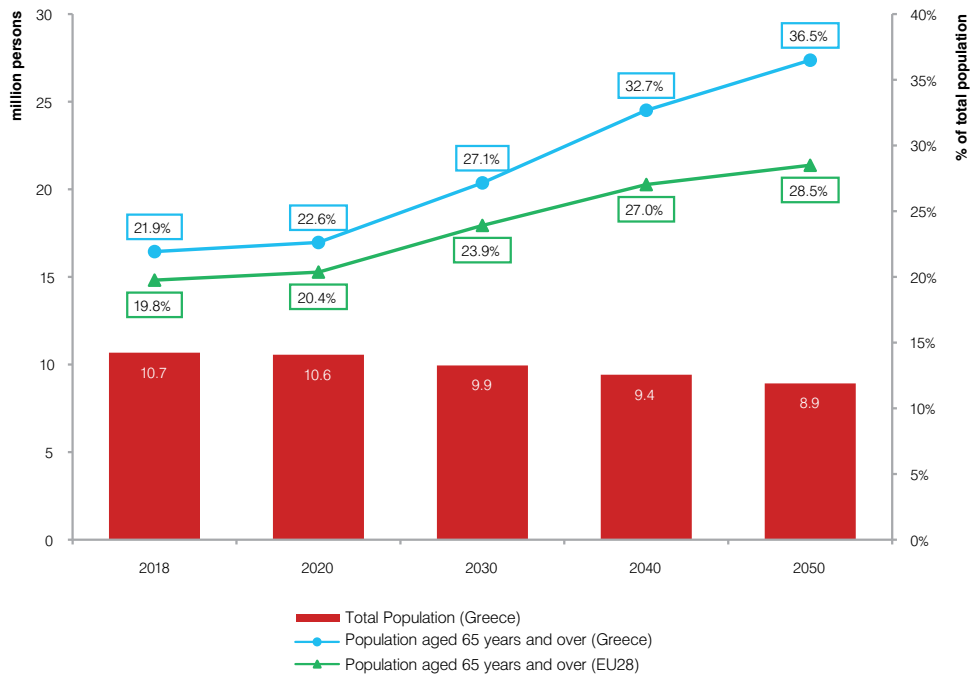
Figure 9: Life expectancy at birth (years) Greece-EU22-Southern countries (2016)



SOURCE: OECD, Statistics 2018, data processing IOBE *Southern countries (Italy, Spain, Portugal)

Based on the latest revision from Eurostat, the steady decline of the population is expected to continue until 2050. In 2018, the percentage of people aged 65 and above in Greece is expected to increase from 22.6% of the total population in 2020 (21.8% in Southern counties, 20.4% in EU28) to 36.5% in 2050.

Figure 10: Population aged 65 and above (% total population) Greece-EU28

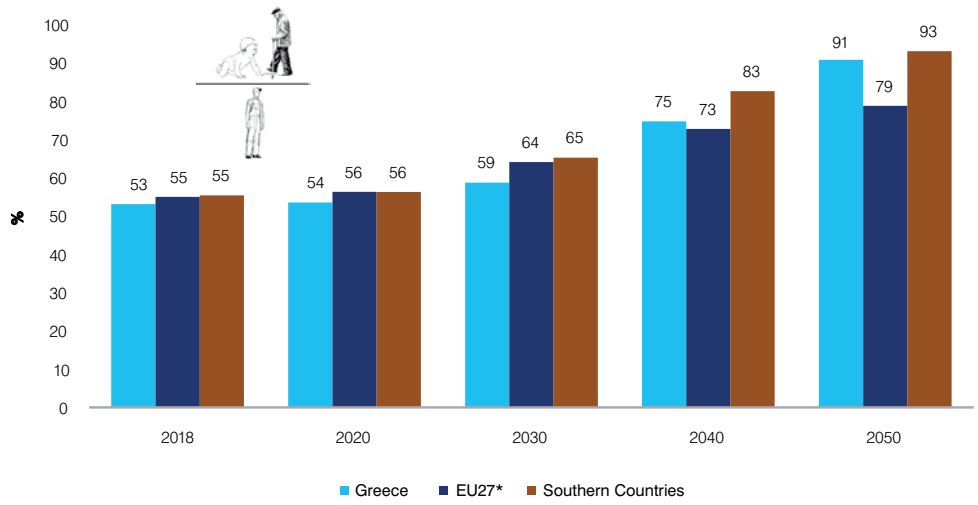


SOURCE: Eurostat, Population Projections, 2018, data processing IOBE *Not included the possible legalization of migration from 2015 onwards

3.4 DEPENDENCY RATIO

The demographic changes directly affect population's dependency ratio. In Greece, nearly half of the population is dependent on the other half, and this proportion is expected to grow, signaling deterioration and increased pressure on the social security system, following the general trend of the developed countries. In 2018, Greece's dependency ratio reaches 53%, meaning that for every 2 active people there is 1 inactive, close to EU28 average (55%) and close to the average of Southern countries (55%). According to the United Nations, the dependency ratio in Greece is estimated to reach 91% by 2050.

Figure 11: Dependency ratio (%) Greece-EU27-Southern countries

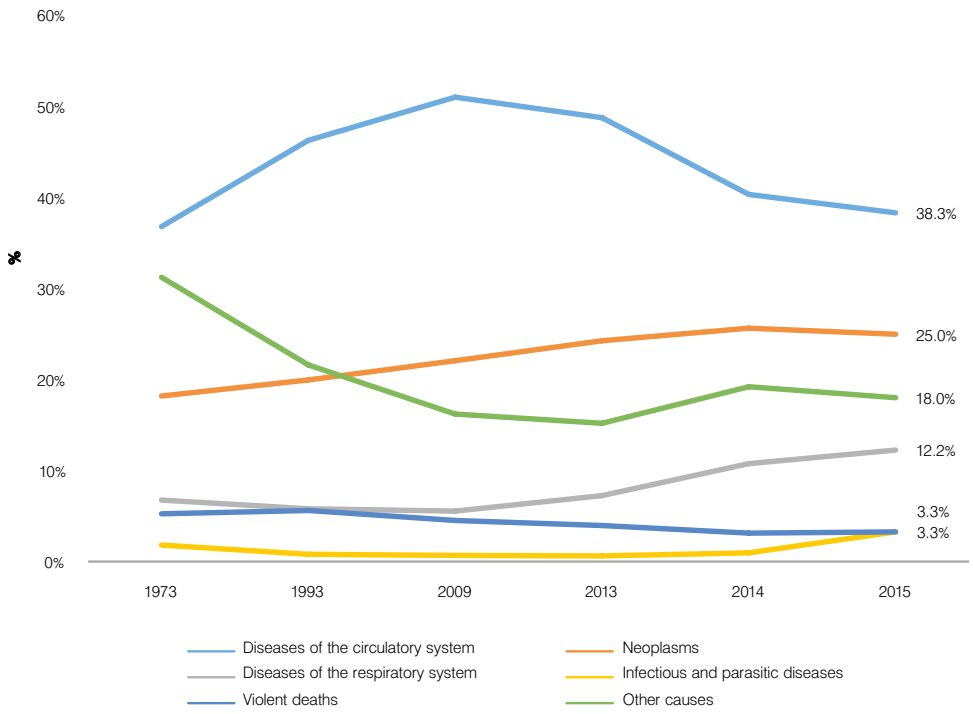


SOURCE: United Nations, World Population Prospects: The 2018 Revision, data processing IOBE, Southern countries (Italy, Spain, Portugal)
*EU27 (non available data for Cyprus). Dependency population ratio shows the number of dependents (aged 0-14 and over the age of 65) to the total active population (aged 15-64). A high ratio means that the overall economy faces a greater burden in supporting the ageing population. This indicator is on an upward trend in advanced economies, reflecting rising life expectancy and declining birth rates.

3.5 CAUSES OF DEATH-CHRONIC DISEASES-PREVENTION

Over time, a significant increase in the deaths due to circulatory system diseases is recorded, responsible for 38.3% of total deaths, despite the decline in recent years, while increase in neoplasms is recorded, accounting for 25.0% of total deaths. Interestingly, the increase in the share of diseases of the respiratory system after 2009, after a stabilization period, and finally the violent deaths and infectious and parasitic diseases compose a small part of the total deaths.

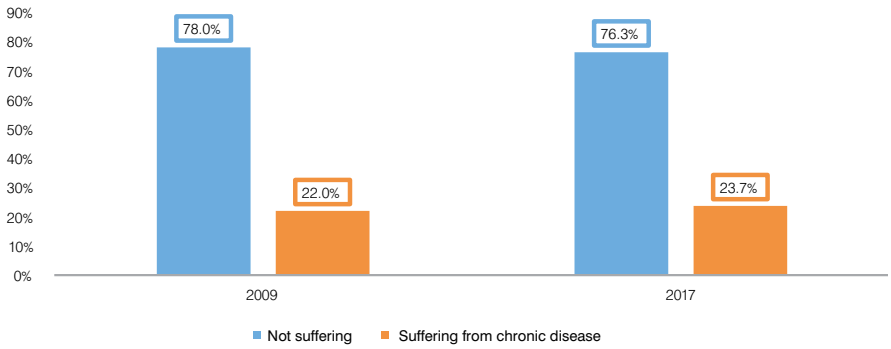
Figure 12: Causes of death (% of total deaths) - Greece



SOURCE: EL.STAT., 2018 data processing IOBE *Pursuant to the 9th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-10) the following are included: cases when it is stated that an investigation by a medical or legal authority has not determined whether the injuries are accidental, suicidal or homicidal; deaths caused by injuries inflicted by law-enforcing agents (including military) on duty in the course of attempting to enforce the Law; deaths caused by injuries during war operations. Other causes: Diseases of the digestive system, Diseases of the genitourinary system, Diseases of the nervous system and sense organs, Endocrine and metabolic diseases, nutrional deficiencies and immune disorders

According to EL.STAT., two out of ten persons (23.7%) aged 16 years and over reports suffering from a chronic illness or health problem. Chronic illness or health problem. A chronic illness or health problem is reported by approximately three out of ten women (25.6%) and by two out of ten men (21.7%).

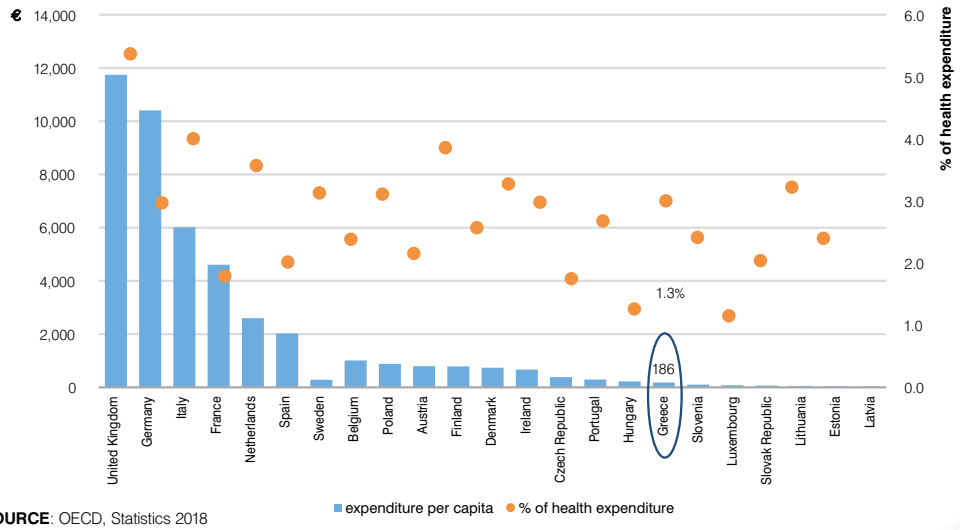
Figure 13: Percentage of population suffering from chronic health problem or chronic disease, 2009 and 2017



SOURCE: EL.STAT.. 2018. Chronic illness or health problem mean illnesses or health problems which have lasted, or are expected to last, for 6 months or more, with or without medication

In 2016 the per capita spending on prevention in Greece reached €186, while the highest was in the UK (€11,743)

Figure 14:Prevention expenditure per capita and as a share (%) of total health expenditure, Greece-EU23 (2016)



SOURCE: OECD, Statistics 2018

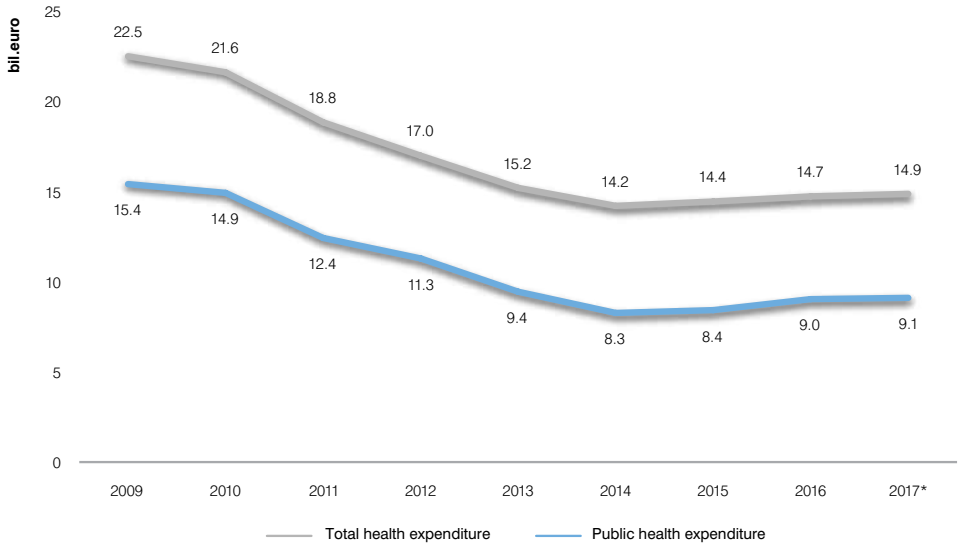
CHAPTER 4

DEMAND SIDE: HEALTH AND PHARMACEUTICAL EXPENDITURE

4.1 FUNDING ON HEALTH EXPENDITURE

In 2017, total health expenditure in Greece amounted to €14.9 bil., out of which €9.1 bil. composes public health expenditure and €5.8 mil private health expenditure.

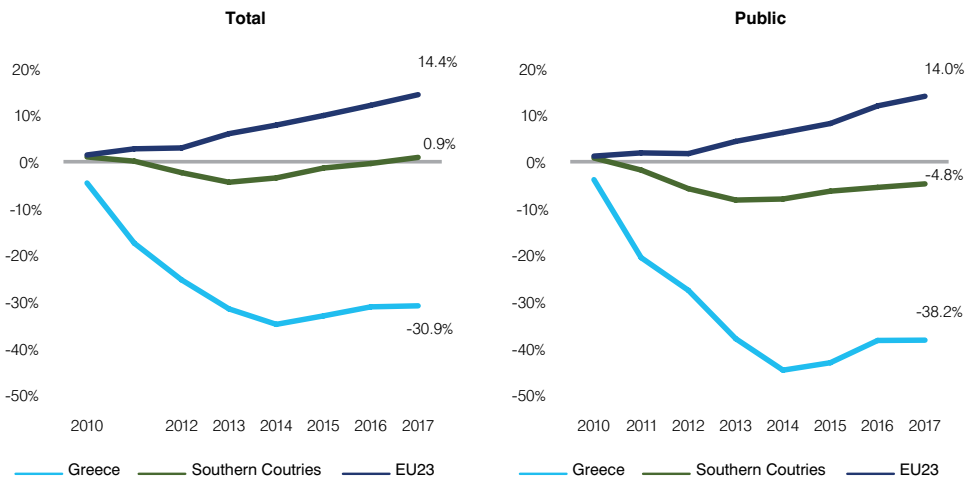
Figure 15: Total and public health expenditure (bil.€)



SOURCE: System of Health Accounts (SHA) 2016, EL. STAT.,2018, OECD Health Statistics, 2018. data processing IOBE* For 2017 is estimated percentage. For the definitions of total and public funding on health expenditure, see Annex 7. Data are in current prices

The index of GDP cumulative change in total health expenditure showed a decline of -0.9% in Southern countries, while an increase of +14.4% was recorded in EU23 (a decrease of -30.9% in Greece during the same period) Similarly, a cumulative decline of -4.8% was recorded in public health expenditure in Southern countries, while an increase of +14.0% was noted for EU23 (-38.2% decrease in Greece during the same period).

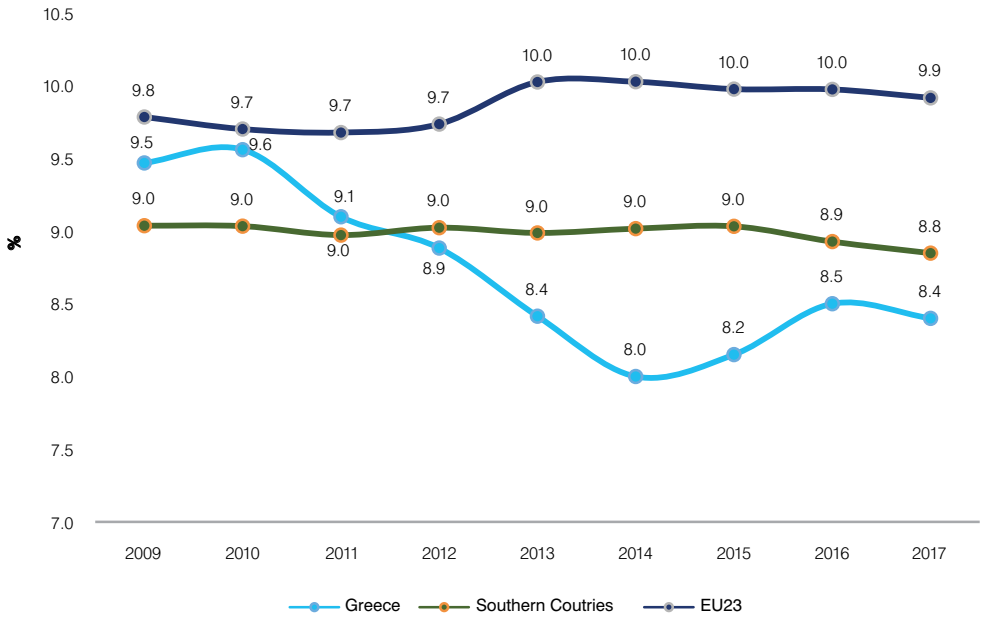
Figure 16: Index of cumulative change on health expenditure (%) Greece-EU23-Southern countries



SOURCE: System of Health Accounts (SHA) 2016, OECD Health Statistics, 2018, IOBE data processing Southern countries (Italy, Spain, Portugal). Percentage changes between 2009 and 2017 have been calculated in the Fixed –rate Price Data ($ 2010 PPS, OECD).

In Greece, total health expenditure as a percentage of GDP accounted to 9.5% (2009) and decreased at 8.4% (2017), indicative of a faster reduction in health expenditure compared to GDP reduction during the same period.

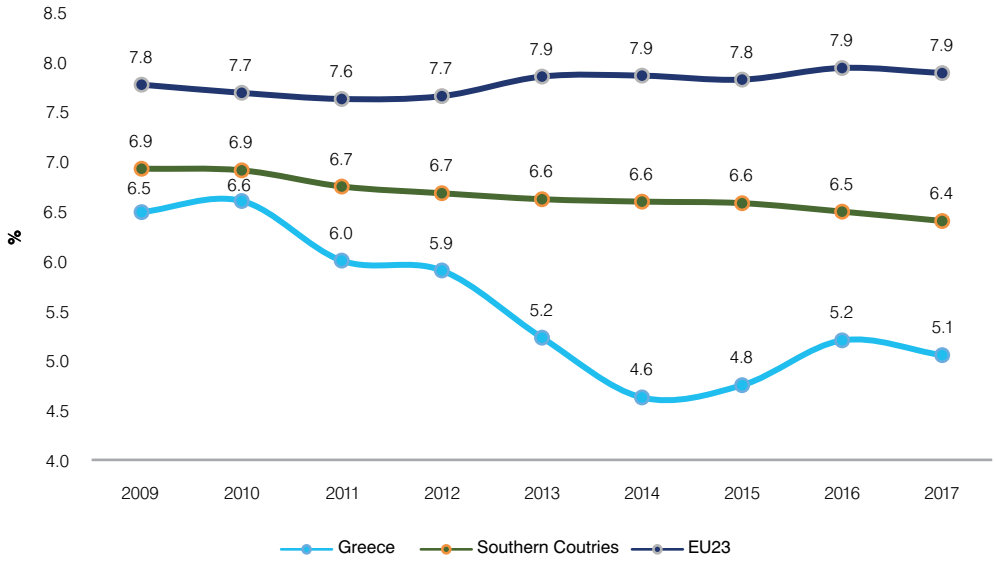
Figure 17: Total health expenditure (% GDP) Greece-EU23-Southern countries



SOURCE: System of Health Accounts (SHA) 2016, EL.STAT., 2018, OECD Health Statistics, 2018, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-23: (not available data for Bulgaria, Croatia, Cyprus, Romania and Malta)

Public health expenditure as a percentage of GDP in Greece amounted to 5.1% in 2017 compared to 6.5% in 2009. This evolution shaped the rate of public health expenditure in Greece below EU23 average (7.9%), which remains almost stable during 2009-2017. In Southern countries that implemented economic adjustment programs, the percentage was at 6.4% for 2017.

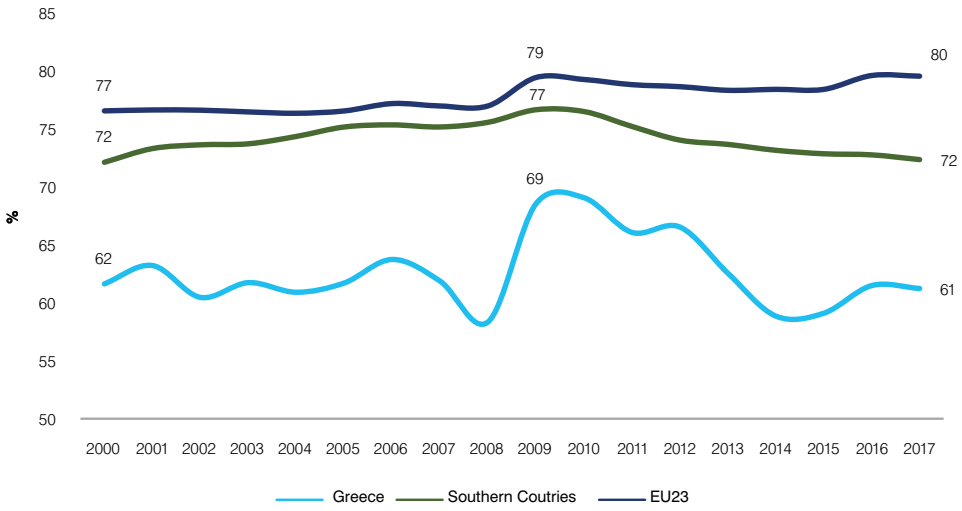
Figure 18: Public health expenditure (% GDP) Greece-EU23-Southern countries



SOURCE: System of Health Accounts (SHA) 2016, EL. STAT., 2018, OECD Health Statistics, 2018, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-23: (not available data for Bulgaria, Croatia, Cyprus, Romania and Malta)

Public health expenditure accounts for 61% of total funding for expenditure health in 2017, compared compared to 69% in 2009, remaining below the EU23 average and Southern countries.

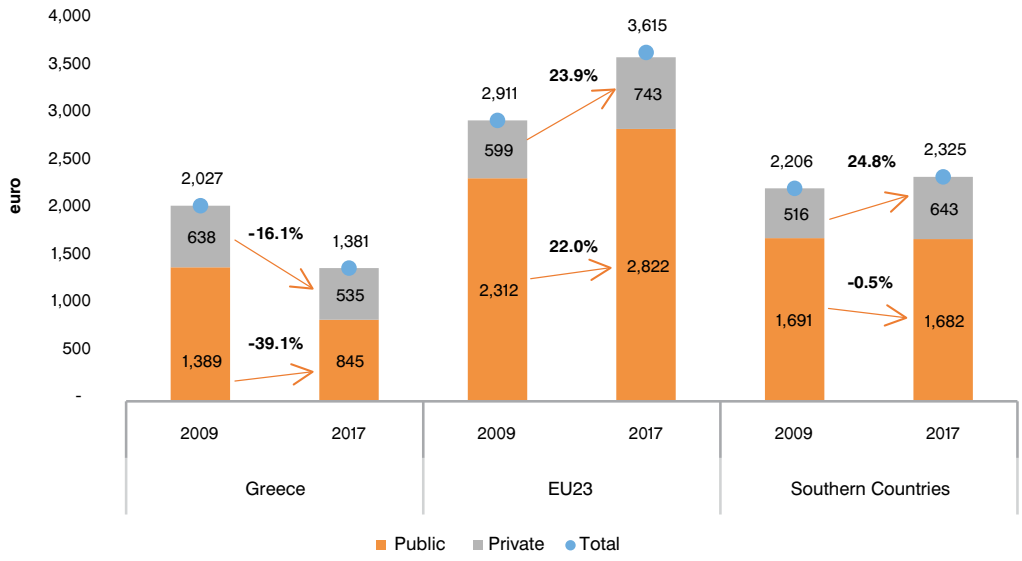
Figure 19: Public health expenditure (% of total expenditure) Greece-EU23-Southern countries



SOURCE: OECD Health Statistics, 2018, data processing IOBE. Southern countries (Italy, Spain, Portugal)

Total health expenditure per capita in Greece amounted to €1,381 in 2017 compared to €2,027 in 2009, that is €944 less than the average of Southern countries. Public health expenditure per capita declined in Greece by -39.1% between 2009 and 2017 and amounted to €845 compared to an increase of +22.0% in EU23 and a slower decline in Southern countries of -0.5% during the same period.

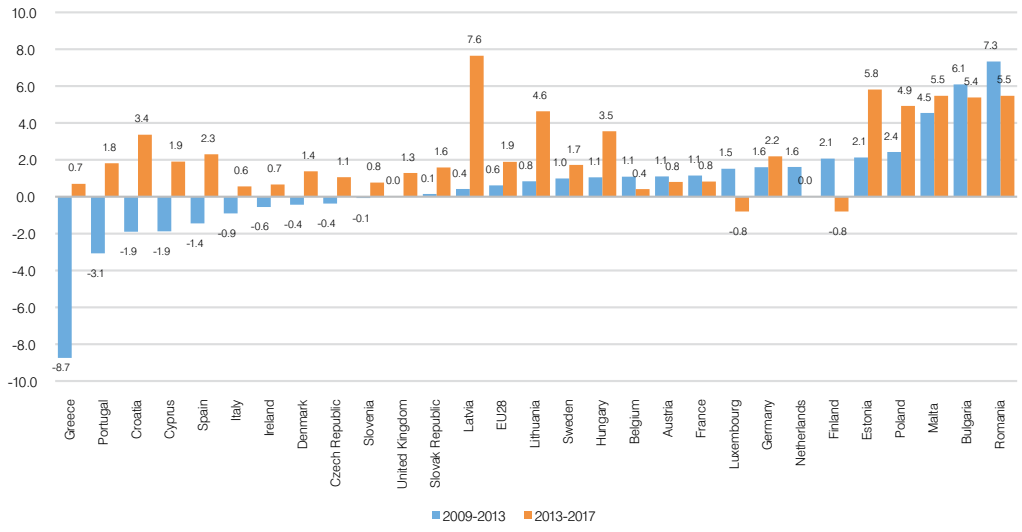
Figure 20: Total per capita health expenditure Greece-EU23-Southern countries



SOURCE: OECD Health Statistics, 2018, data processing IOBE Southern countries (Italy, Spain, Portugal). EU 23 due to unavailability of data for other countries

Over the period 2009-2013, the per capita health expenditure in Greece declined by -8.7%, the largest among OECD countries, with an increase of 0.7% in the period 2013-2017.

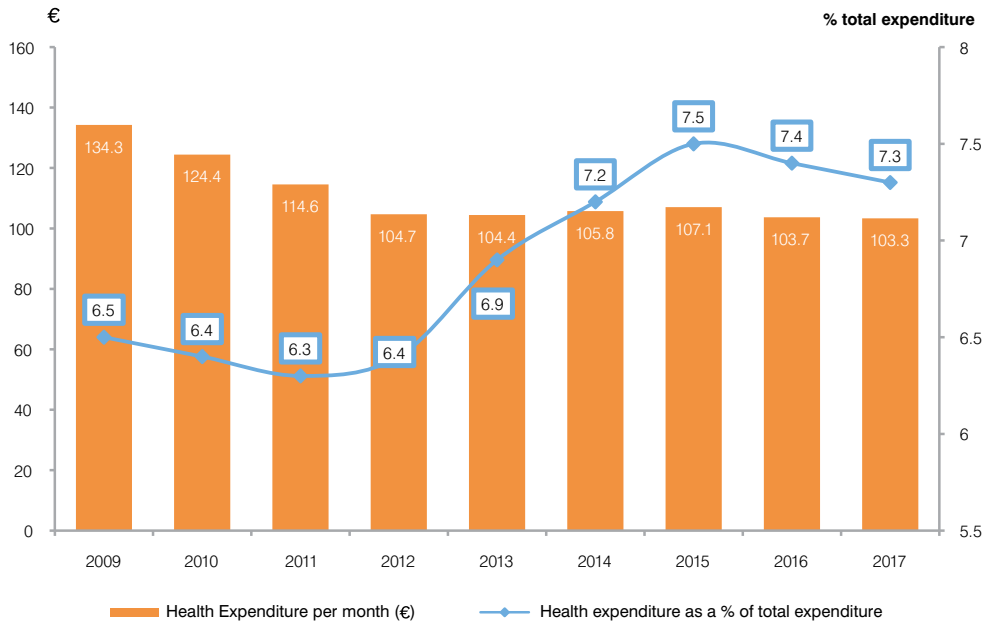
Figure 21: Average per capita health expenditure evolution, OECD counties, 2009-2013 and 2013-2017



SOURCE: OECD Health Statistics, 2018

Households' monthly health expenditure was contracted by -23% during 2009-2017, when it reached €103.3, which accounted for 7.3% of total household expenditure (6.5% in 2009), indicating households' reduced purchasing power and increased participation in health expenditure.

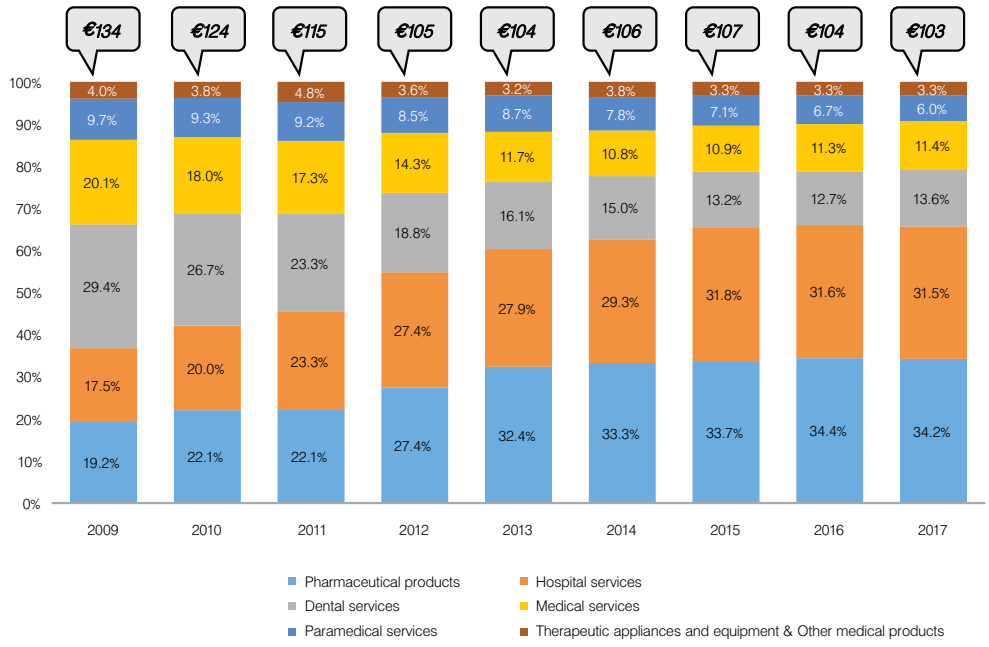
Figure 22: Health expenditure of households (e) per month-Greece



SOURCE: EL. STAT., 2018, data processing IOBE. Household Budget Survey, which is conducted annually by the ELSTAT, provides information for the composition of total household spending, according to various socioeconomic characteristics of each household.

During the economic crisis period, there was a shift of household expenditure mainly towards pharmaceutical and hospital care. Specifically, from €103 monthly health expenditure per household, 34.2% refers to pharmaceuticals and 31.5% to hospital services, 13.6% to dental services and 11.4% to other medical services.

Figure 23: Breakdown of household health expenditure (%) per month - Greece

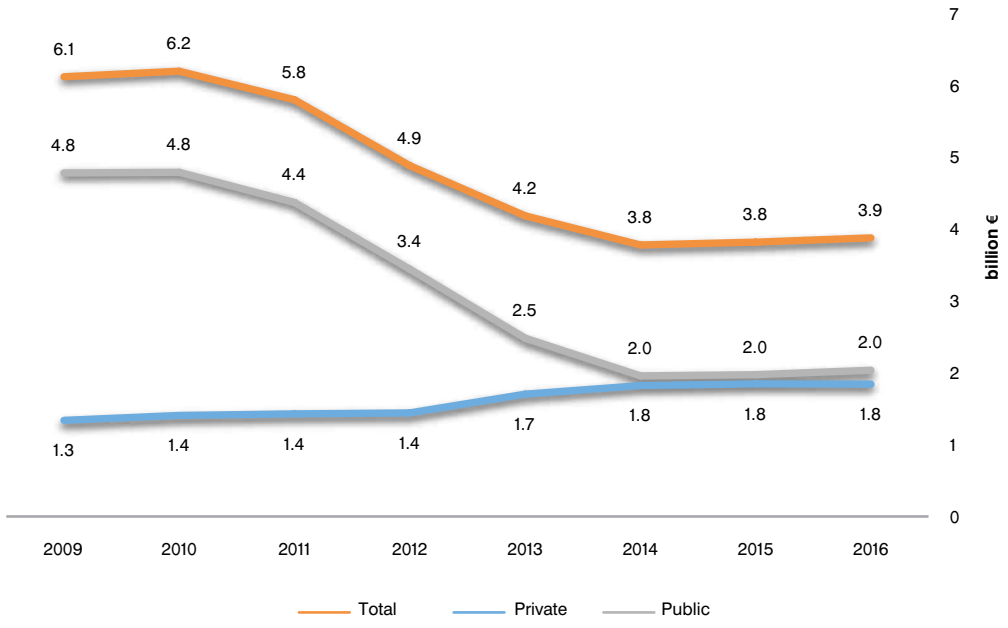


SOURCE: EL. STAT., 2018, data processing IOBE

PHARMACEUTICAL EXPENDITURE

Total expenditure for pharmaceuticals and other medical non-durable goods accounted for €3.9 bil. in 2016, recording a decrease of -37.5% compared to 2009. Correspondingly, public expenditure for pharmaceuticals and other medical non-durable goods from €4.8 bil. in 2009 amounted to €2.0 bil. in 2015, recording a further decline of -58.7%, while private expenditure for pharmaceuticals and other medical non-durable goods increased from €1.3 bil. in 2009 to €1.8 bil. 2016.

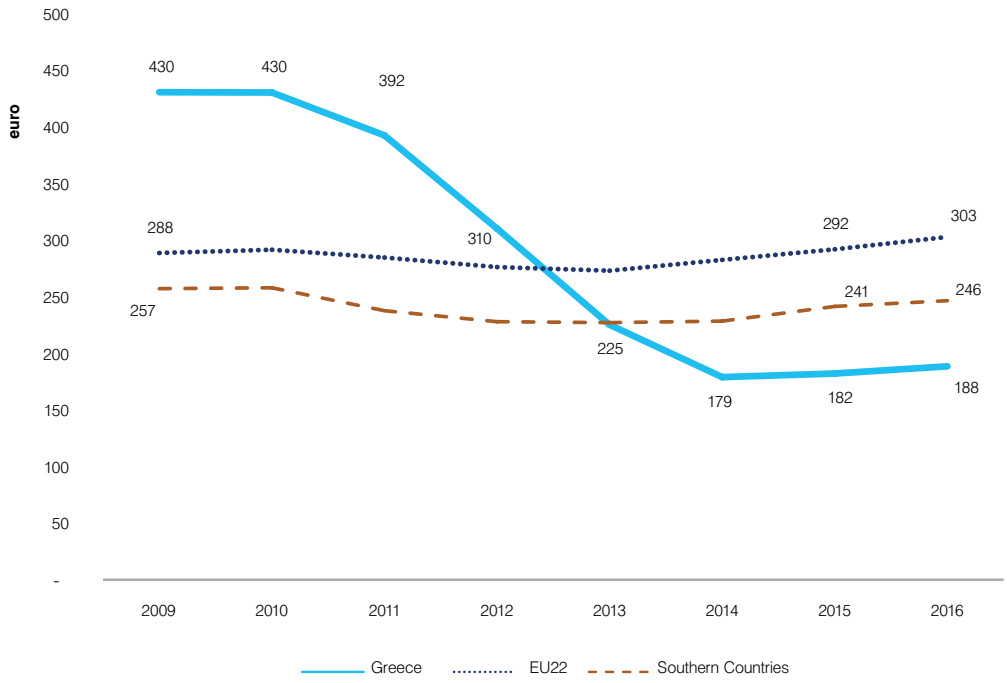
Figure 24: Total expenditure for pharmaceuticals and other medical non-durable goods (bil. €)-Greece



SOURCE: System of Health Accounts (SHA) 2016, EL. STAT., 2018, data processing IOBE. Expenditure for pharmaceuticals and other medical goods, as reported in the OECD and SHA, includes expenditure on final consumption by outpatients of prescription and non-prescription pharmaceuticals, on-patented and generics. Medical goods are also recorded in the same category (see Annex 7)..

Similarly, a downward trend was observed in public per capita expenditure for pharmaceuticals and other medical non-durable goods, from €430 in 2009 to €188 in 2016. Public per capita expenditure for pharmaceuticals and other medical non-durable goods in EU22 increased from €288 in 2009 to €303 in 2015 approximately €115 higher than Greece, while in Southern countries was €246.

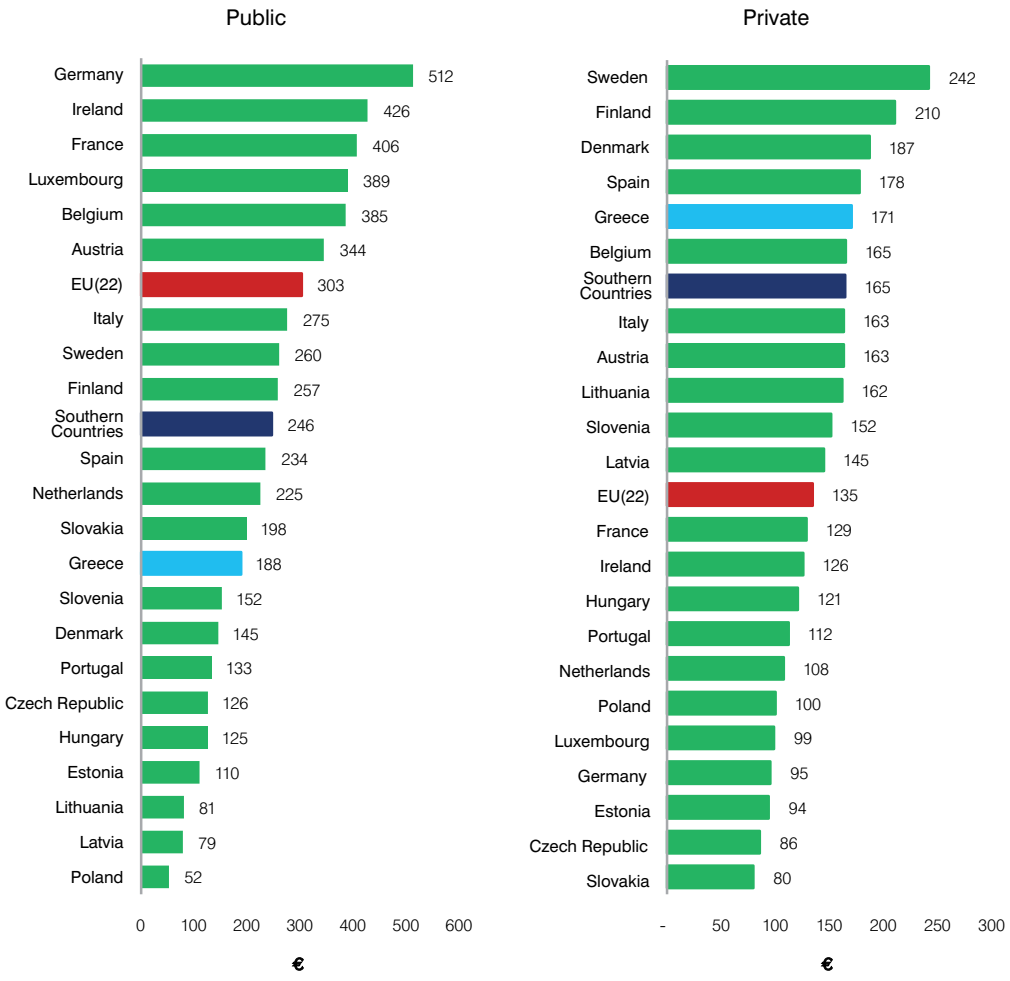
Figure 25: Public per capita expenditure for pharmaceuticals and other medical non-durable goods Greece-EU22-Southern countries



SOURCE: OECD Health Statistics 2018, Eurostat 2018, data processing IOBE. Southern countries (Italy, Spain, Portugal).EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta, UK)

More specifically, the higher public per capita expenditure in 2016 for pharmaceuticals and other medical non-durable goods was recorded in Germany, Ireland and France, while Greece (€188) is below the average of EU22 (€303). On the contrary, private per capita expenditure for pharmaceuticals and other medical non-durable goods in Greece (€171) is higher than the average of EU22 (€135), ranking 5th among EU countries.

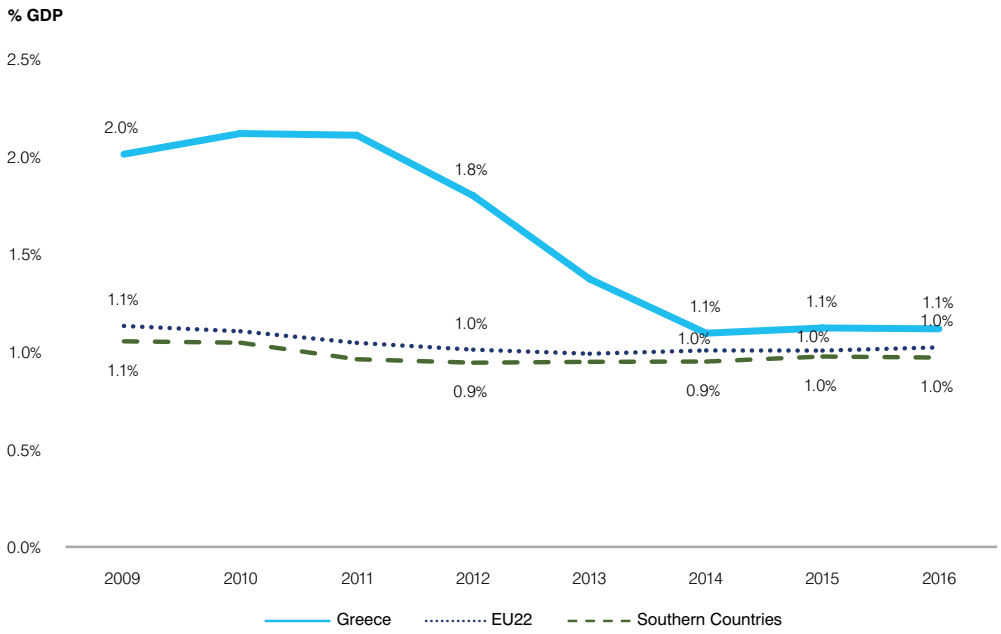
Figure 26: Public & private per capita expenditure for pharmaceuticals and other medical non-durable goods (2016)



SOURCE: OECD Health Statistics 2018, Eurostat 2018, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta, UK).

Public expenditure for pharmaceuticals and other medical non-durable goods as a percentage of GDP in Greece is estimated at 1.1% of GDP in 2016 compared to 2% in 2009, close to EU22 and Southern countries.

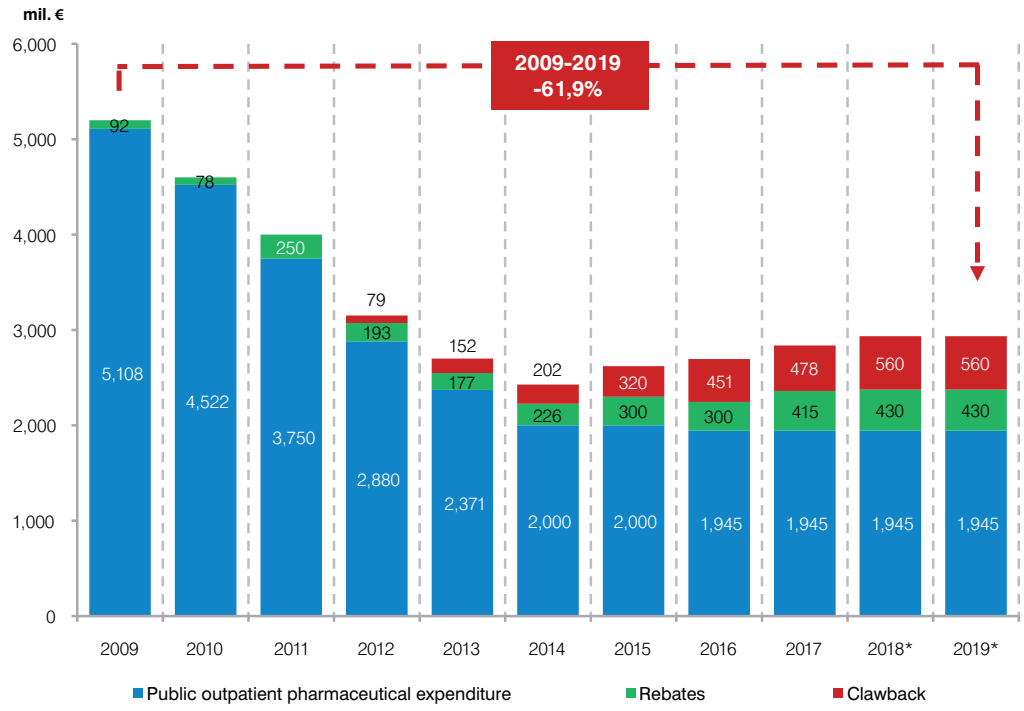
Figure 27: Public expenditure for pharmaceuticals and other medical non-durable goods (% GDP) Greece-EU22-Southern countries



SOURCE: OECD Health Statistics 2018, Eurostat 2018, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta, UK).

Public outpatient pharmaceutical expenditure amounted to €1,945 bil. in 2018 (and 2019) compared to €5.1 bil. in 2009, resulting in an overall decrease by -61.9%. Accordingly, there was a significant increase in the contribution of pharmaceutical industry through mandatory returns and discounts (clawback and rebates). Specifically, in 2018 industry's contribution was €990 mil. recording an increase of 11% in comparison to previous year.

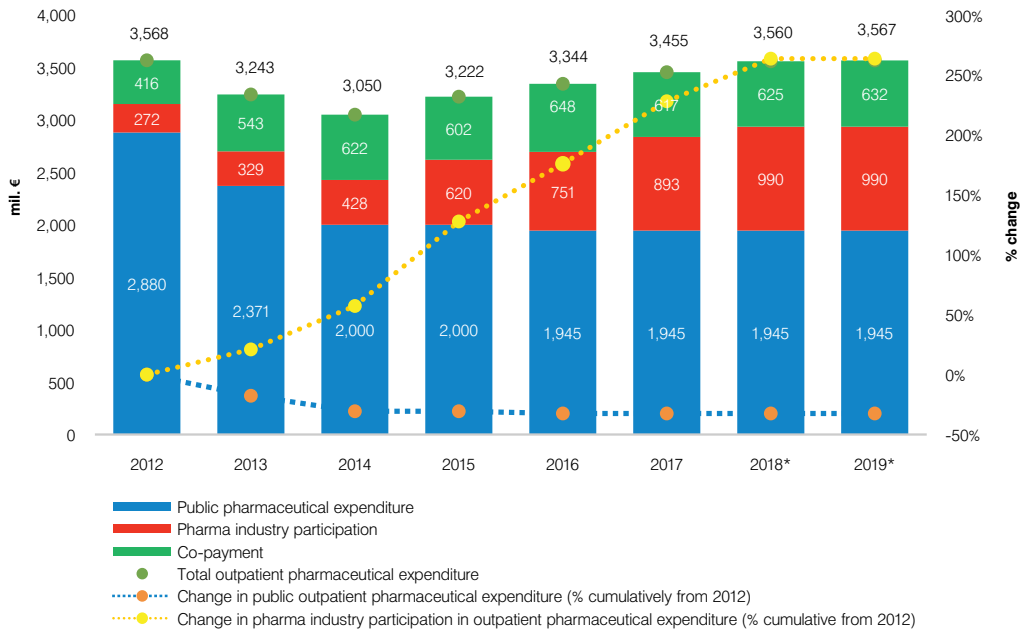
Figure 28: Outpatient pharmaceutical expenditure (excluding patients' contribution)



SOURCE: EOPYY 2012-2018, State Budget 2014-2018, data processing IOBE-SFEE Note: Although the pharmaceutical companies sell at ex-factory prices, the state calculates the clawback at retail prices. For 2018 and for 2019 clawback and rebates are estimations

Total outpatient pharmaceutical expenditure (including estimated patients' contribution) amounted to ~€3.6 bil. in 2018. However, the significant decline in public outpatient pharmaceutical expenditure by 61% during 2009-2017 resulted in a 263% increase on industry's contribution over the same period.

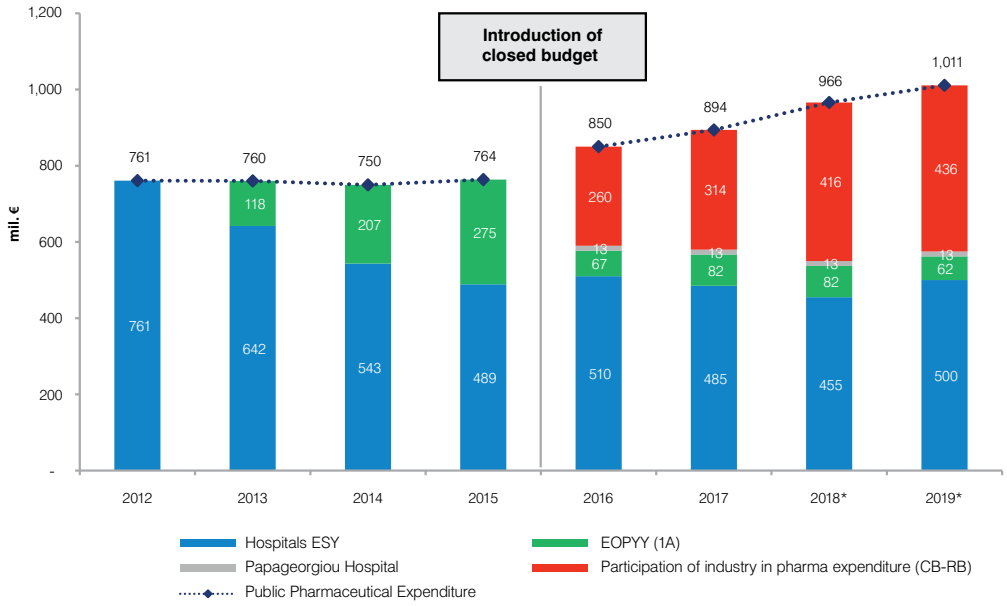
Figure 29: Total outpatient pharmaceutical expenditure (including industry's' and patients' contribution)



SOURCE: EOPYY 2012-2018, State Budget 2014-2018, data processing IOBE-SFEE Patient participation: What the patient pays to the reimbursed market (i.e. 0%, 10%, 25%) and the burden resulting from the difference between Retail Price - Reimbursement Price.

Public hospital pharmaceutical expenditure was set at €530 mil. for 2018, decreased by -31% compared to 2015 (€764 mil.), before introducing closed budget. The reduction of public hospital pharmaceutical expenditure resulted in a shift towards industry (through clawback and rebates), estimated at €436 mil. for 2018.

Figure 30: Public hospital pharmaceutical expenditure and industry's contribution



SOURCE: EOPYY 2012-2018, State Budget 2014-2018, data processing IOBE-SFEE. Note: Estimations for 2018 for industry's contribution according to 2017. Public hospital pharmaceutical expenditure: data from ESY.net and EOPYY for 2013-2015.

4.3 PATIENTS' CONTRIBUTION

Public pharmaceutical expenditure includes the expenditure of all the social security funds for prescribed medicines, i.e. medicines that are reimbursed by Social Security Funds (SSF). Net public pharmaceutical expenditure is the final amount paid by the SSFs after deduction of rebates & clawback.

Private pharmaceutical expenditure includes co-payment rates of insured persons for reimbursed medicines (statutory participation & the additional charge incurred when the patient selects a medicine with a higher Retail Price than the Reimbursement Price), the private costs of consumers (patients) for non-reimbursed pharmaceuticals and related products but also for those medicines they pay or choose to pay in full, as well as the reimbursement of part of the expenditure by private insurance companies.

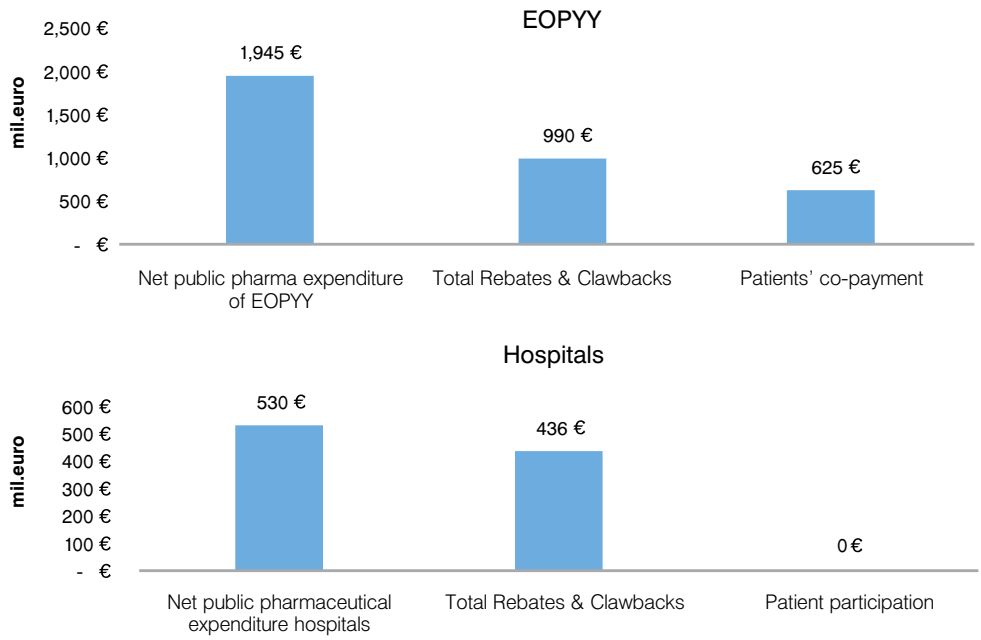
Patient co-payment in reimbursed medicines is distinguished in:

- Statutory co-payment: 0% or 10% or 25% of the reimbursement price
- Charge resulting from the difference between Retail Price and Reimbursement Price when the patient selects a medicine with Retail Price Higher that the Reimbursement Price

Other private payments for a medicine contain:

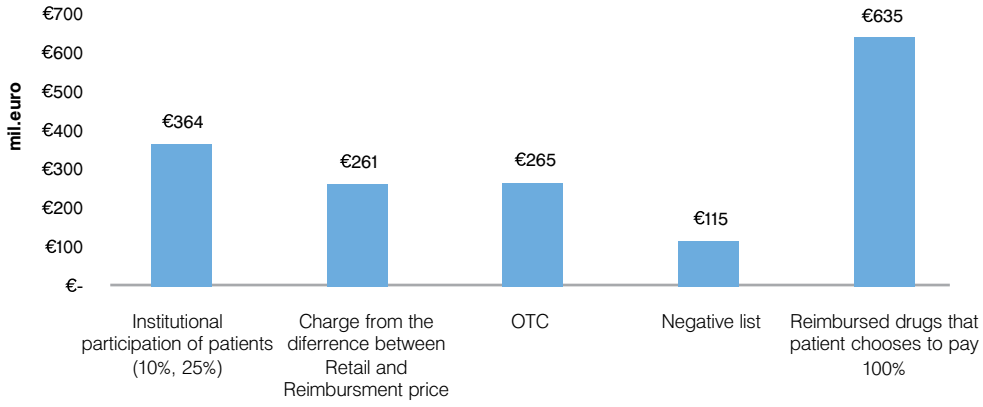
- either non-prescription medicines (OTC)
- either prescribed medicines which are not reimbursed (Negative List)
- either prescribed medicines of the reimbursement list, but the patient chose not to use his insurance right and chose to pay them entirely out of his pocket.

Figure 31: Patient participation in the reimbursement market (2018*)



SOURCE: State Budget, company notes, data from IDIKA, data processing SFEE *estimation

Figure 32: Total private pharmaceutical expenditure (2018 *)



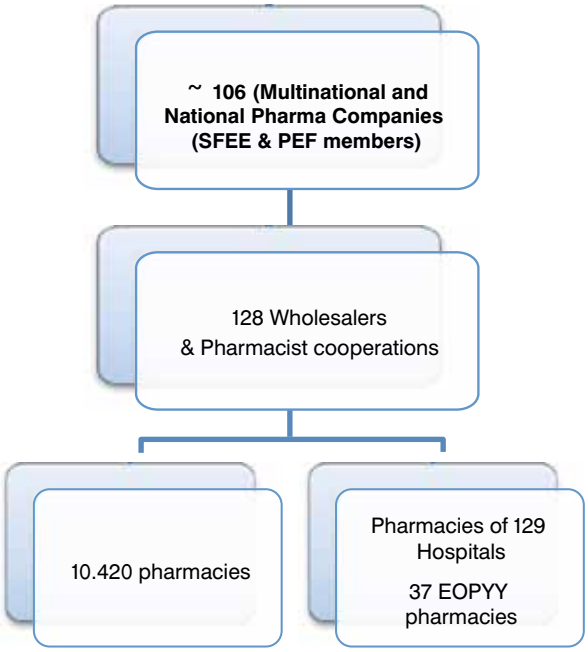
SOURCE: Data from IDIKA (Institutional Patient Participation), OTC and Negative list, SFEE calculations based on IQVIA data (MAT3/2018)
*estimation

CHAPTER 5

SUPPLY SIDE: PHARMACEUTICAL INDUSTRY AND ECONOMY

5.1 SUPPLY CHAIN FOR PHARMACEUTICAL PRODUCTS IN GREECE

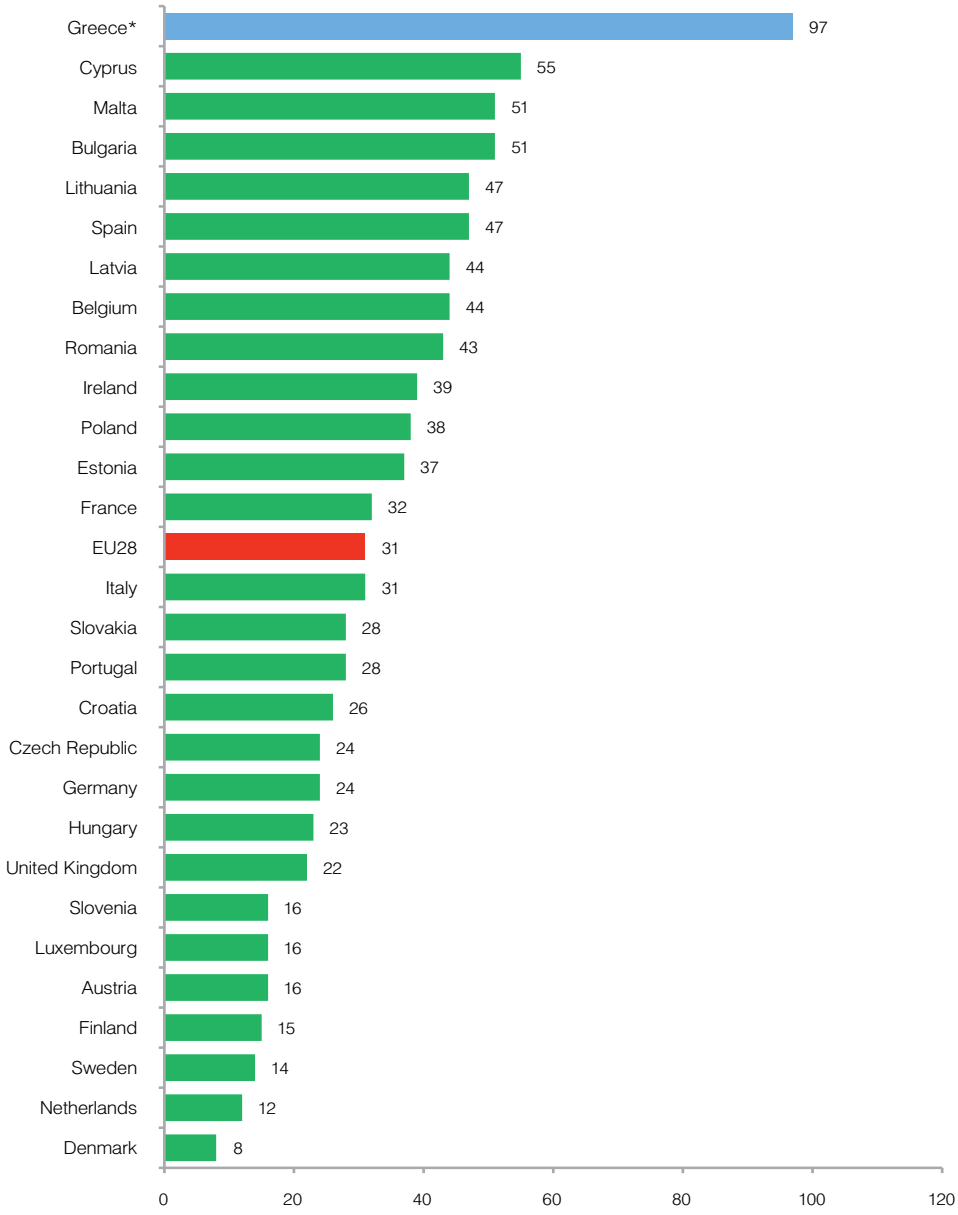
The production and distribution of pharmaceuticals is one of the most dynamic sectors in the Greek industry. Supply chain for pharmaceutical products is comprised of pharmaceutical companies (both manufacturers and importers), wholesalers (both storage and distribution) and pharmacies. More specifically, pharmaceutical products, except products for hospital use only which are provided through sales to hospitals, follow the path: pharmaceutical company - wholesalers - pharmacy.



SOURCE: EL.STAT., EOPYY, PanHellenic Association of Pharmaceutical Wholesalers

With a pharmacy density of 97 pharmacies per 100,000 inhabitants. Greece comes first among the EU-28 average of 31 pharmacies per 100,000 inhabitants.

Figure 33: Number of pharmacies per 100,000 inhabitants. EU 28 (2017)



SOURCE: ABDA. German Pharmacies, Figures Data Facts 2018, EL.STAT.,2018 * Data for Greece come from the latest available EL.STAT. data.

In 2017, 10,420 pharmacies operated in Greece, out of which 3,739 pharmacies (36%) were located in the Region of Attiki. The number of wholesalers in 2016 amounted to 128 in 2016 compared to 120 in 2016.

Figure 34: Pharmacies and wholesalers- Greece

SOURCE: EL.STAT.,2018 *Preliminary data

EOPYY PHARMACIES

EOPYY initially operated 5 pharmacies in Attica region and 1 in Thessaloniki, supplying high cost medicines without copayment and without the confirmation of the prescription by the relevant social security fund (except 2 month). Currently, 37 pharmacies of EOPYY are in operation. In other parts of the country, insured citizens can obtain high cost medicines for the treatment of serious diseases (Law 3816/2010) from EOPYY's local health units, after placing an order.

Based on the ministerial decree published in Government Gazette 64/B'/16-01-2014, the list of high-cost, serious diseases pharmaceutical products that fall under the provisions of L.3816/2010 was split into two distinct lists. The first list relates to pharmaceutical products that are only available for hospital use, while the second list includes those pharmaceuticals, which their use begins in the hospital and can be continued on an outpatient setting. EOPYY pharmacies and public hospitals procure products of the first list in hospital price reduced by 5% and the corresponding rebates, while pharmaceuticals of second list followed the way of pricing applied under the provisions set by the Ministry of Health.

By 2015, the majority of high-cost drugs (N.3816 / 2010) was provided by the EOPYY pharmacies and hospital pharmacies.

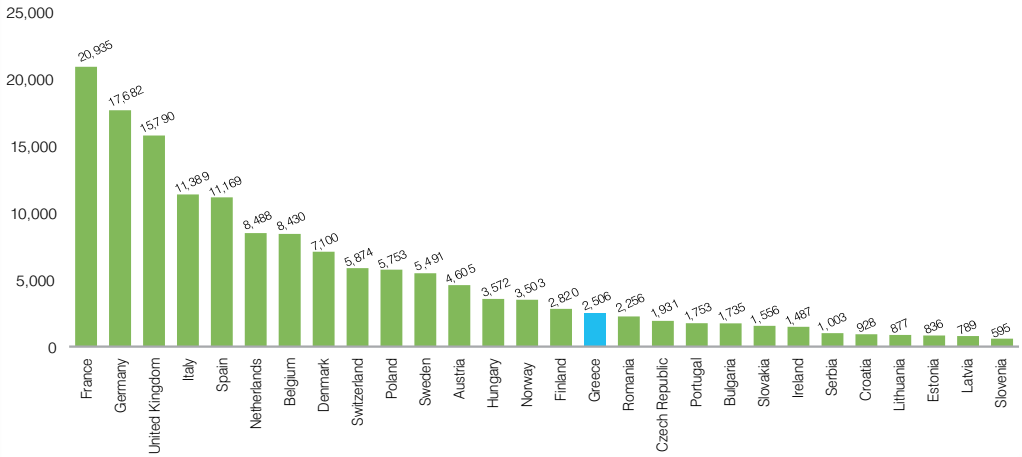
Since January 2016, under the new legislative regulation for hospital clawback (N. 4354 / 12.16.2015, Section D, Article 41), all high-cost medicines that their use is hospital only (Annex 1A) are exclusively administered from pharmacies in public hospitals.

EOPYY pharmacies provide exclusively high-cost drugs belonging to Annex 1B and Annex 1A for use only in specific private clinics.

5.2 RESEARCH AND DEVELOPMENT (R&D)

In Greece, 2,506 clinical studies (1,434 completed) were conducted up to 2018, number similar to that in countries such as Finland.

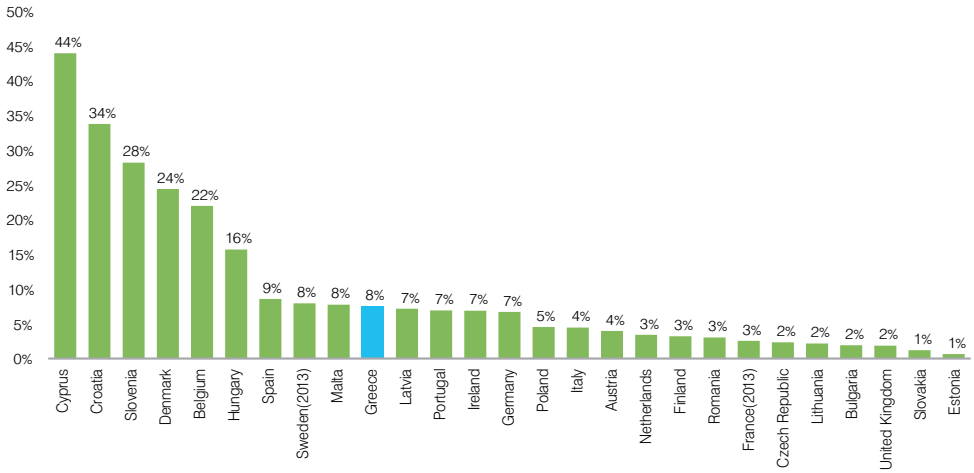
Figure 35: Total number of clinical trials, all phases and stages (2018)



SOURCE: Clinical trials.gov, 2018

Research & Development expenditure in the pharmaceutical industry accounts for 12% of total R&D expenditure in Greece, share higher than the rest of Southern countries.

Figure 36: Pharmaceutical R&D expenditure (% of total R&D expenditure)

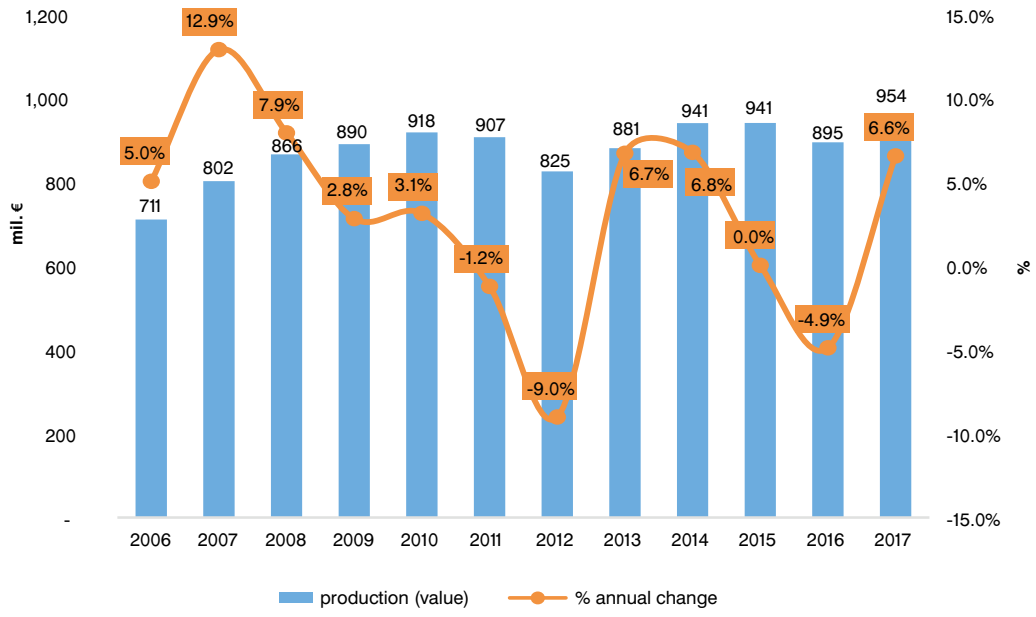


SOURCE: Eurostat, 2018, data processing IOBE

5.3 PRODUCTION

According to Prodcom database (Eurostat) in terms of value (ex-factory prices), pharmaceutical production in Greece was estimated at €954 mil. in 2017, approximately 6.6% higher than in 2016.

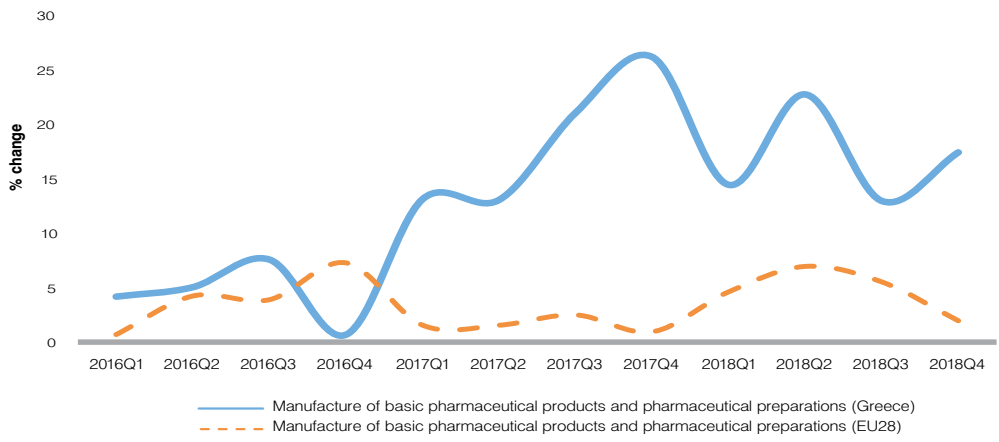
Figure 37: Production of pharmaceutical products (mil. €)



SOURCE: Eurostat 2018, PRODCOM Database. *Any changes based upon review of data from Eurostat

The industrial index of domestic pharmaceutical production, recorded a significant increase in 2017 and 2018, indicating that the value of domestic pharmaceutical production for 2018 will be at higher levels.

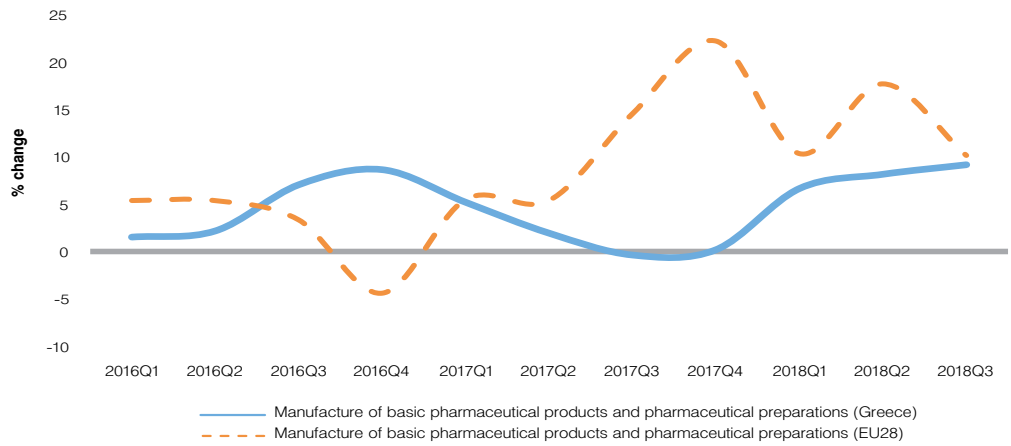
Figure 38: Industrial index of domestic pharmaceutical production (2015=100)



SOURCE: EL.STAT., 2019, seasonally adjusted and adjusted data by working days

The turnover of pharmaceutical production is rising in 2018, and the third quarter, against a fall in 2017, in combination to the highest increase in the index production is estimated to have fallen.

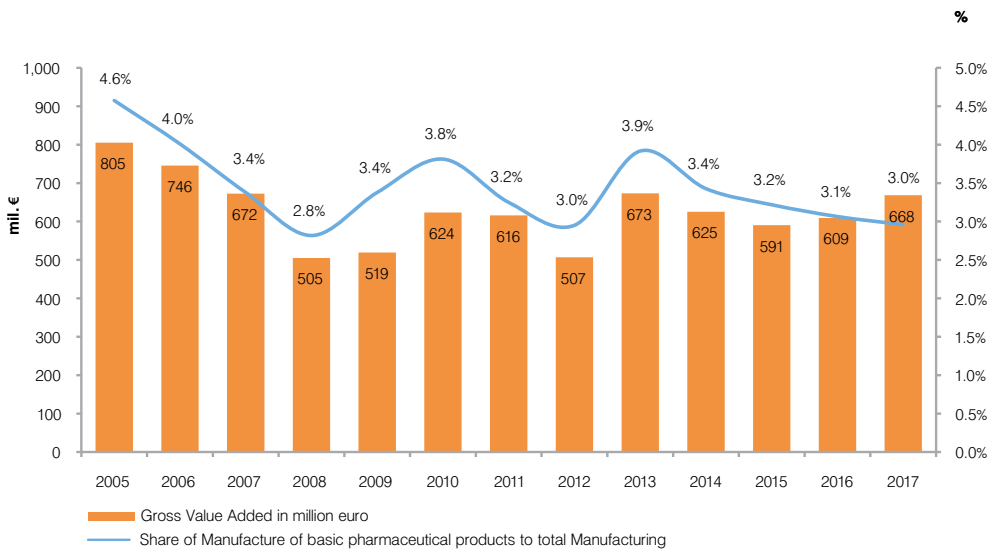
Figure 39: Turnover index in domestic pharmaceutical production (2015=100)



SOURCE: EL.STAT., 2019, seasonally adjusted and adjusted data by working days

The gross Value Added (GVA) of domestic pharmaceutical production is estimated at €668 mil. in 2017, higher by 9.7% compared to 2016, and amounted with a share of 3.0% in total manufacturing sector.

Figure 40: Gross Value Added of pharmaceutical production and share in manufacturing (%)

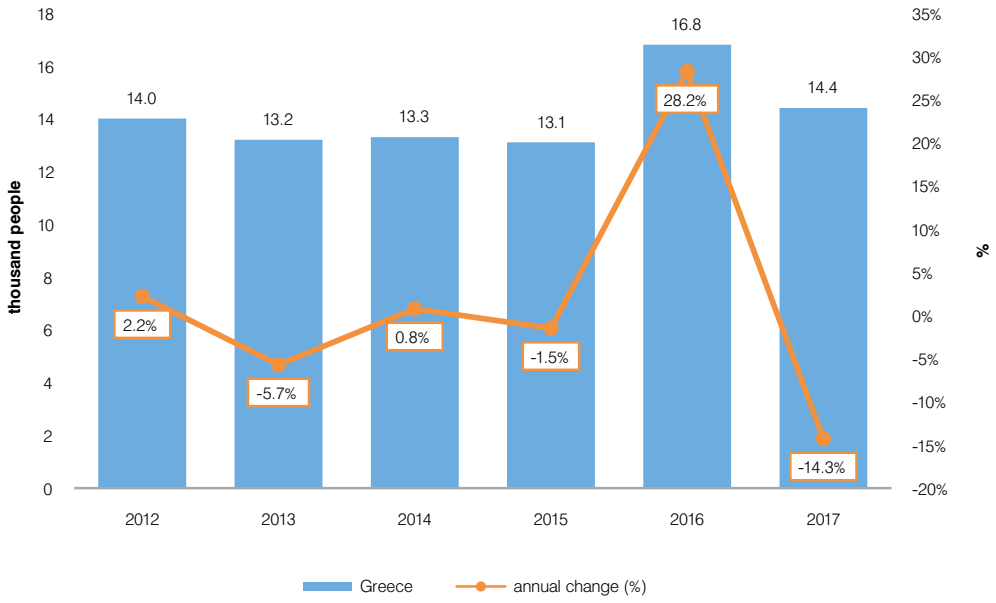


SOURCE Eurostat, 2018, data processing IOBE*Any changes based upon review of data from Eurostat* C21: Manufacture of basic pharmaceutical products and pharmaceutical preparations include only the companies active in the production of medicines and pharmaceutical preparations. In C21 manufacturing companies are not included firms that belong to subsector 46.46 Wholesale of pharmaceutical products

5.4 EMPLOYMENT

According to Eurostat, 14.4 thousand people were employed in pharmaceutical production in Greece in 2017, demonstrating a decrease of -14.3% compared to 2016.

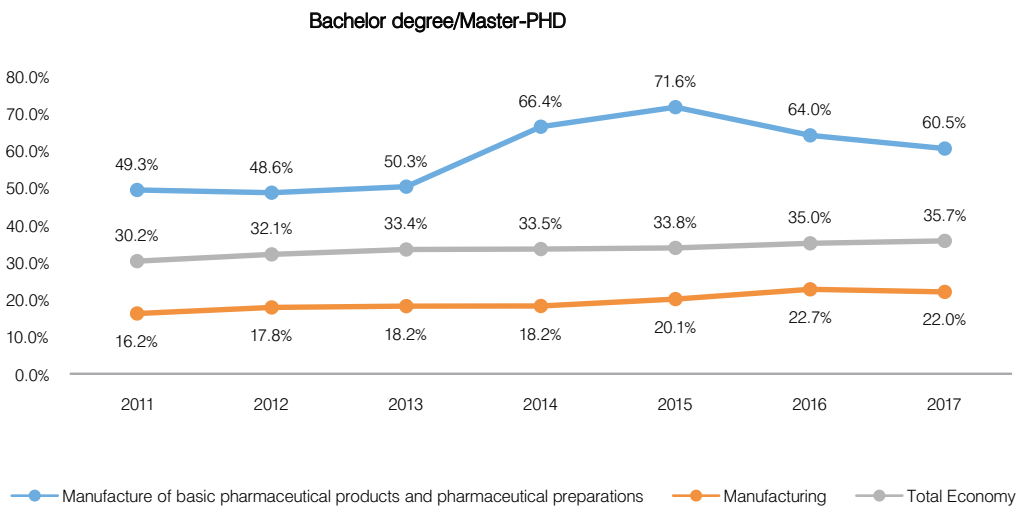
Figure 41: Employment in pharmaceutical production (thousand people)



SOURCE: Eurostat, 2018, Labour Force Survey, 2018, data processing IOBE * Employees in the wholesale sector of the wider health sector are not included

At the same time, according to the International Standard Classification of Education (ISCED) for 2017, the educational background of people working in the pharmaceutical industry was very high, with 60,5% of total employees in pharmaceutical production with university education compared to 35,7 % in the manufacturing and 22.0%, in the total economy, indicating the high educational training of the employees in the pharmaceutical industry. This difference shows the importance of domestic pharmaceutical production as a preventive sector in the brain drain.

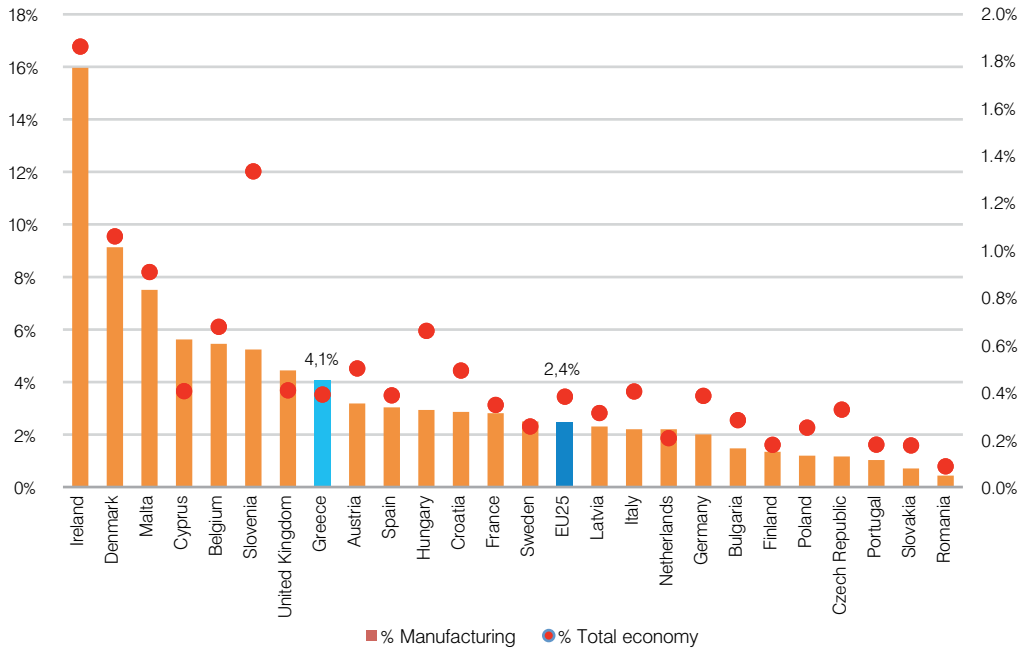
Figure 42: Number of employees with tertiary education in pharmaceutical production (%)



SOURCE: EL.STAT., 2018, Employees Tertiary Education of total employment International Standard Classification of Education (ISCED 2011)

In 2017, employment in the pharmaceutical sector represents 0.4% of total employment of the Greek economy, while this share increases to 4.1% with regards to employment in the manufacturing overall. The share of manufacturing is higher than the respective average in EU25 (2.4%).

Figure 43: Employment in the production of pharmaceutical products (% manufacturing and economy) EU25 (2017)



SOURCE: Eurostat. Labour Force Survey 2018, data processing IOBE. Note: No data available for Lithuania, Luxembourg and Estonia

An important measurement for employed people is the recording time in Full Time Equivalent (FTE), by calculating total employment assuming that all workers are employed full-time. According to the available data, pharmaceutical industry recorded a decline of employment in FTEs by -7.2% during 2010-2017 compared to total manufacturing (-23.2%), indicating that employment in pharmaceutical sector shows inflexibility.

Simultaneously, total wage cost decreased by -12.3% compared to much larger decline in manufacturing (-34.3%). At the same time, the average hourly wage stood at €10.3 for pharmaceutical industry compared to €6.7 in total manufacturing and €5.3 for the total economy.

Table 1: Change in employment and wages 2010-2017

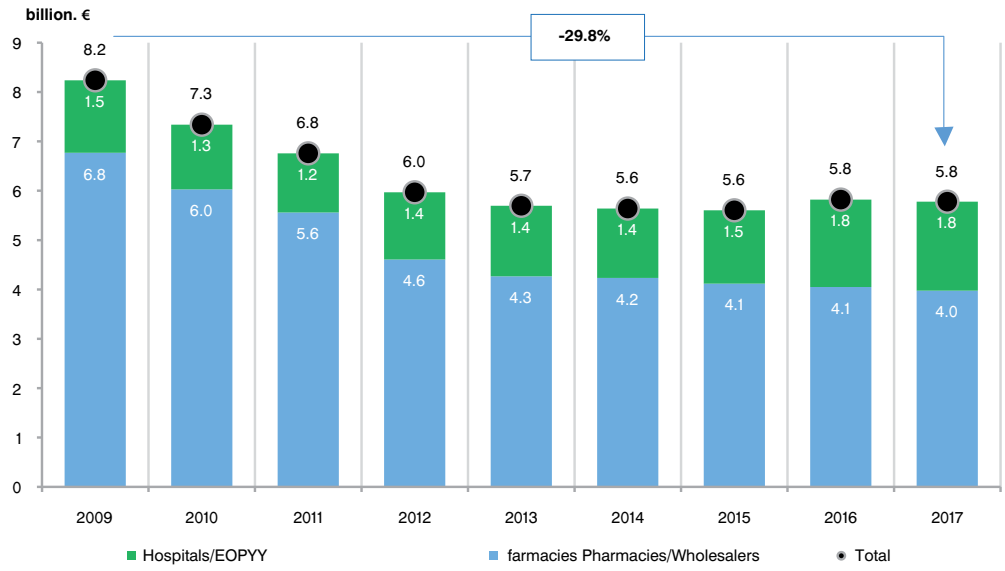
	Employment % change (FTE)	Compensation of employees	Average hourly wage (2017)
Total Economy	-10.8%	-29.7%	5.3 €
Manufacturing	-23.2%	-34.3%	6.7 €
Pharmaceutical production	**-7.2%**	**-12.3%**	**10.3** €

SOURCE: Eurostat. National Accounts, 2019, data processing IOBE

5.5 SALES

Sales of pharmaceutical products to pharmacies & wholesalers (in values) amounted to €4.0 bil. in 2017, showing a reduction of -1.8% compared to 2016. On the contrary, sales to hospitals & EOPYY pharmacies amounted to €1.8 bil. in 2017 presenting an increase of +1.9% compared to previous year. Approximately, 68.8% of total sales were supplied to wholesalers and private pharmacies, while the remaining 31.2% to hospitals and EOPYY pharmacies.

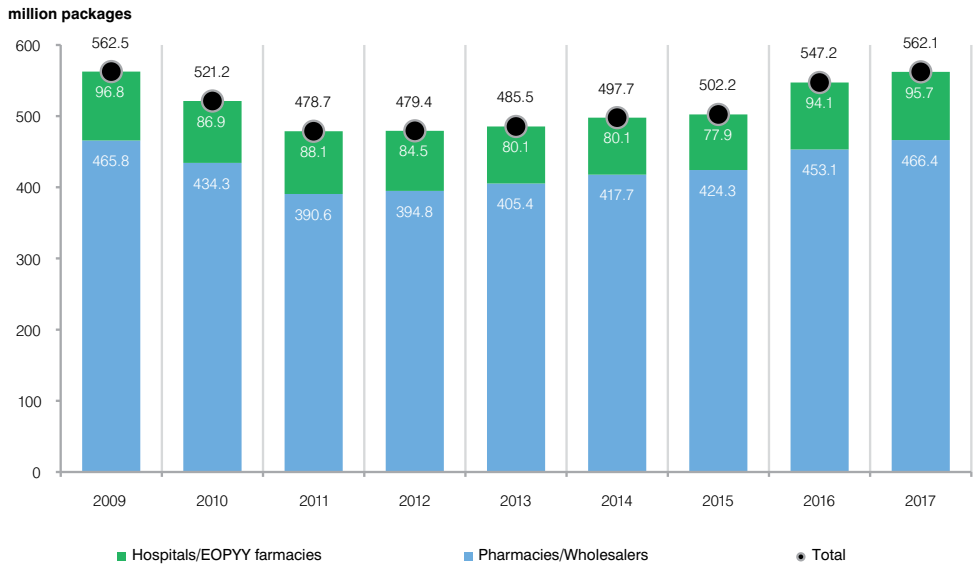
Figure 44: Sales of pharmaceutical products in values (bil. €)-Greece



SOURCE: EOF, 2018 (Pharmacies/Wholesalers at retail prices and Hospitals at hospital prices) Total pharmaceutical sales recorded monthly by the National Organization of Medicines (EOF) and include pharmaceutical sales by pharmaceutical companies to hospitals (at hospital prices) and Wholesalers / Pharmacies (at retail prices). Sales also recorded in terms of number of packages. Parallel exports in 2017 were €385 mil. and are included here.

Regarding the number of packages, an increase of +2.7% was recorded in 2017 compared to 2016 (562.1 mil. packages) with an increase of +2.9% in pharmacies/wholesalers and an increase of 1.7% in hospitals/EOPYY pharmacies was depicted.

Figure 45: Sales of pharmaceutical products in volume (mil. packages) - Greece



SOURCE: EOF, 2018 *Possible smaller packaging replacements

Table 2: Parallel exports in values 2008-2017

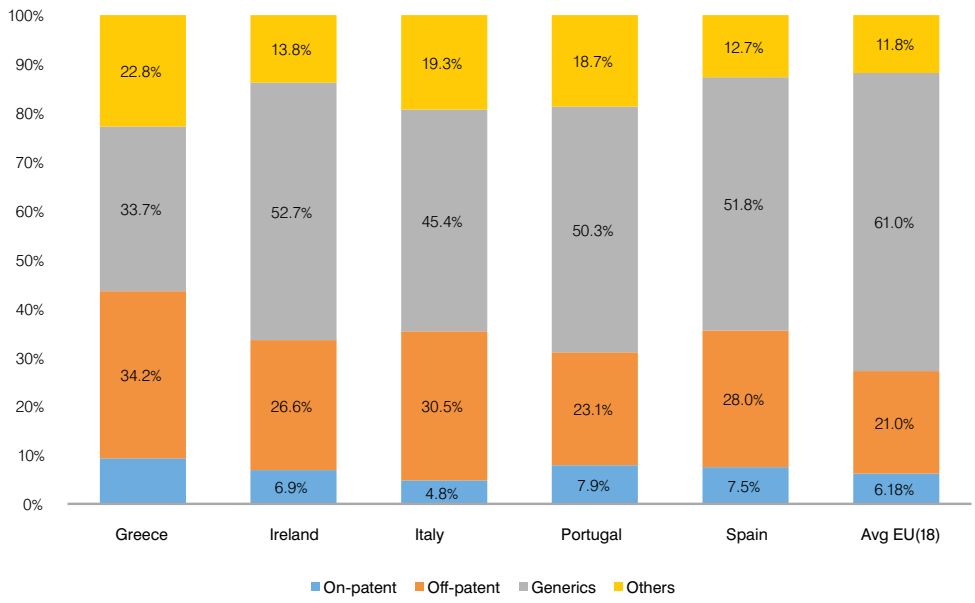
	Value (in mil.€)
2008	607,560,542
2009	649,656,941
2010	626,108,697
2011	485,959,647
2012	415,067,547
2013	328,018,383
2014	306,697,909
2015	401,635,357
2016	400,275,317
2017	384,487,265

SOURCE: EOF, 2018

Pharmaceutical products can be classified according to their patent protection status. According to IQVIA (MAT08/2018), the penetration rate of patent protected medicinal products (on patent) in terms of volume account for 9.3% of the market, which is higher than the average of EU18 (6.18%) which can be partly justified by their significantly lower prices in Greece compared to EU18 countries (€0.91 per unit on average compared to €2.05)

Respectively, the market share of non-protected pharmaceutical products amounted to 67.9% (off-patent 34.2% & generics 33.7%). It is worth noting that the penetration rate of off-patent is higher than the average of EU18 (19.8%), while penetration rate of generics is much lower than the average of EU18 (61.0%).

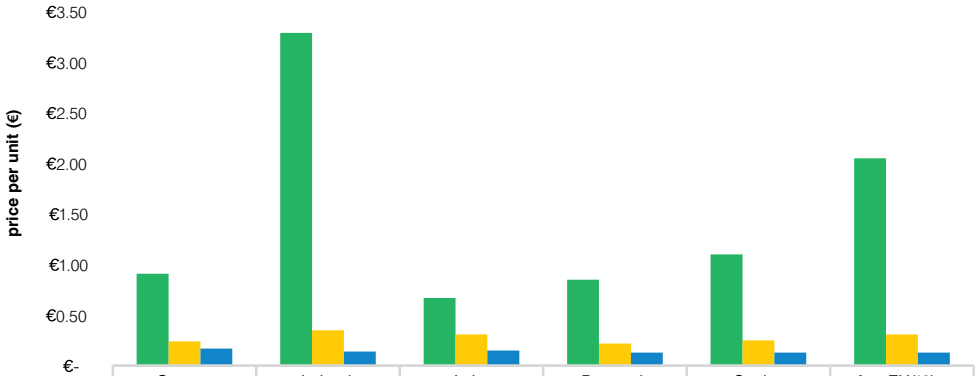
Figure 46: Penetration of pharmaceuticals in EU18, 2018 (in volume) based on patent status



SOURCE: IQVIA, 08/2018 Note1: only retail sales are included for all countries 2 The EU average is made up of available data from 18 countries: Greece, Ireland, Italy, Portugal, Spain, Belgium, France, Germany, Netherlands, UK, Finland, Norway, Sweden, Austria, Czech Republic, Hungary, Poland and Slovakia

According to IQVIA (MAT08/2018), penetration rate in volume for off patent and generic products is partly justified by significantly lower prices for off patent products in Greece compared to the average of EU18 (€0.24 per unit compared to €0.31) and by slightly higher prices for generic products in Greece compared to the average of EU18 (€0.17 per unit compared to €0.13).

Figure 47: Pricing of pharmaceuticals in EU18, 2018 (price per unit. €) based on patent status

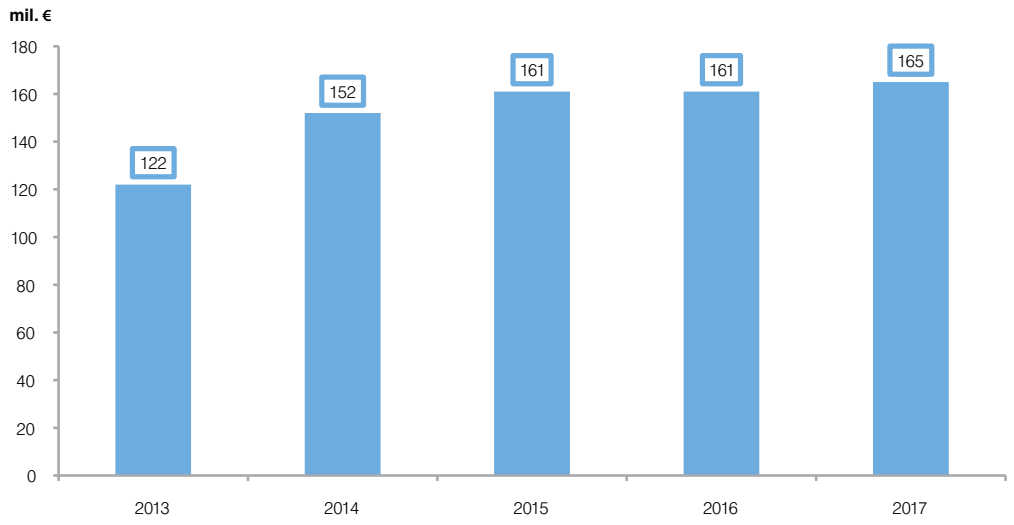


	Greece	Ireland	Italy	Portugal	Spain	Avg EU(18)
On-patent	€0.91	€3.29	€0.67	€0.85	€1.10	€2.05
Off-patent	€0.24	€0.35	€0.31	€0.22	€0.25	€0.31
Generics	€0.17	€0.14	€0.15	€0.13	€0.13	€0.13

SOURCE: IQVIA, 08/2018 Note[1]: only retail sales are included for all countries [2] The EU average is made up of available data from 18 countries: Greece, Ireland, Italy, Portugal, Spain, Belgium, France, Germany, Netherlands, UK, Finland, Norway, Sweden, Austria, Czech Republic, Hungary, Poland and Slovakia

The market of OTC followed an upward trend from 2013 onwards from €122 mil. in 2013 to €165 mil. in 2017, an increase of 35.2%.

Figure 48: OTC sales in value 2013-2017 (in mil. €)



SOURCE: AESGP,2018 *Note: Depending on the source of information used, there may be deviations over EFEX-AESGP data

The general Distribution Medicines (GEDIFA), a subset of OTC (216 of the total 1.582 OTC), are available outside pharmacies and concern analgesics, antipyretics, antipruritic, topical medications, laxatives (to treat constipation) and mouthwashes. Of the self-medication products, analgesics, cough and cold products, digestive products, dermatological products and vitamins recorded the largest sales.

Table 3: Sales self-medication products (mil. €)

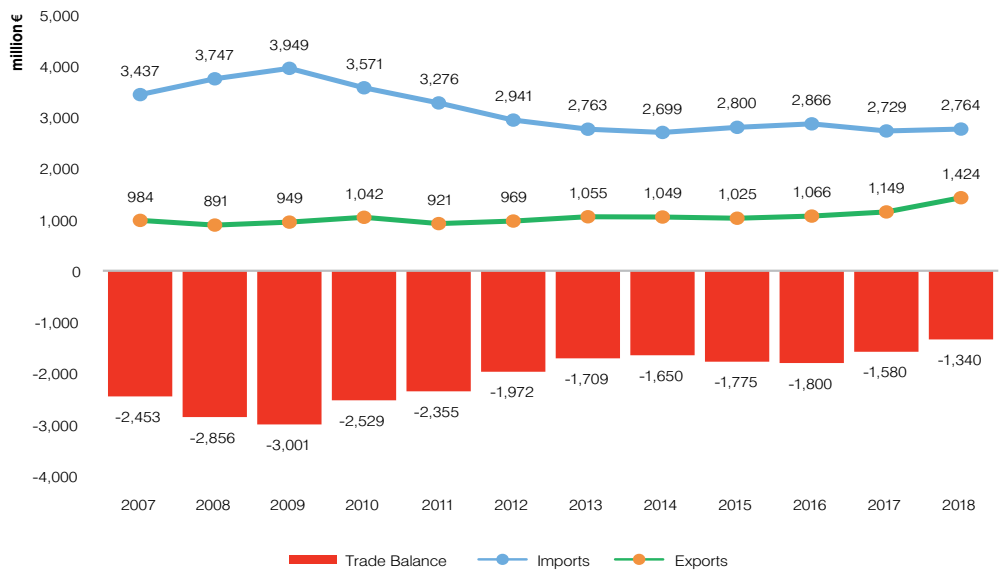
Category	2013	2014	2015	2016	2017	%17/16
Analgesics	60	65	64	65	71	9.2%
Cough & Cold	67	69	66	65	75	13.9%
Digestives & Intestinal	23	24	25	28	32	12.7%
Skin Treatment	33	32	32	32	30	-5.1%
Vitamins & Minerals	62	70	68	67	72	7.2%
Rest categories	81	64	24	83	89	7.7%
Total	**323**	**340**	**335**	**339**	**368**	**8.4%**

SOURCE: AESGP,2018 *Note: Depending on the source of information used there may be deviations over EFEX-AESGP data

5.6 EXTERNAL TRADE

Imports and exports of pharmaceutical products amounted to €2.8 bil. and €1.4 bil. in 2018, increased by 1.3%, and 24% respectively, resulting on a deficit of -€1.3 bil. Pharmaceuticals exports accounted for 4.3% of total Greek exports in 2018 In comparison to 4.0% in 2017. Correspondingly, imports account for 5.0% of the total exports of the country, with downward trend over the last three years.

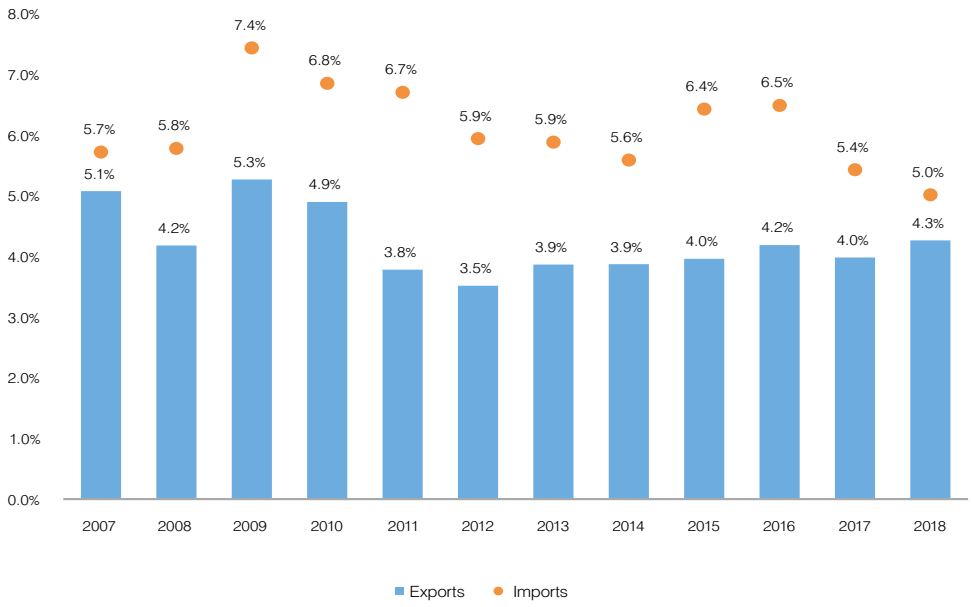
Figure 49: Evolution of pharmaceutical trade balance (mil.€)



SOURCE: Eurostat International trade. EU Trade Since 1988 By CN8,2019, data processing IOBE

Regarding the most important trading partners in the category of pharmaceuticals, on the side of imports is Germany (27%), France (10.7%) and Switzerland (10%), while on the side of exports is again Germany (18.8%), United Kingdom (14.8%) and Cyprus (7.9%). It should be noted that the Greek pharmaceutical industry imports from 61 countries and exports to 141 countries.

Figure 50: Share of pharmaceutical exports-imports (% of total exports-imports)-Greece



SOURCE: Eurostat International trade, EU Trade Since 1988 By CN8,2019, data processing IOBE

5.7 PRICING OF PHARMACEUTICALS

According to Law 4600/2019 (Gazette 43 A '/ 9.3.2019) the pricing system is changing:

Table 4: Pricing system

	Old system	New system
Pricing (on-patent)	First pricing: • Average of 3 lowest EU prices • The product should be priced in at least 3 EU member states ** Biological, bio-similars, hybrid and biotech medicines fall within the same legislative framework.*	First pricing: • Average of 2 lowest different Eurozone prices, the price in each case cannot be lower than daily treatment cost (DTC) • The product should be priced in at least 3 EU member states **MD about the status of biological, bio-similars, hybrid and biotech medicines is pending*
	Re-pricing: Average of the 3 lowest prices in the EU	Re-pricing Average of 2 lowest different Eurozone prices the price in each case cannot be lower than daily treatment cost (DTC). ** • If the price is lower than the lowest price in Eurozone: **Increase of the price** on each re-pricing up to 10% on the price of the preceding price bulletin with a maximum level of the lowest Eurozone price. • If the price is higher than the average of the 2 lowest Eurozone prices: **Price Reduction** on each re-pricing up to 10% on the price of the preceding price list with a lower limit of the average of the 2 lowest different price in Eurozone. Price cannot be lower that the DTC.
Pricing (off-patent)	At the loss of the patent (the lowest of the following values): either 50% or the average of the 3 lowest prices in the EU	Average of 2 lowest different Eurozone prices the price in each case cannot be lower than daily treatment cost (DTC). ** • If the price is lower than the lowest price in Eurozone: **Increase of the price** on each re-pricing up to 10% on the price of the preceding price bulletin with a maximum level of the lowest Eurozone price. • If the price is higher than the average of the 2 lowest Eurozone prices: **Price Reduction** on each re-pricing up to 10% on the price of the preceding price bulletin with a lower limit of the average of the 2 lowest different price in Eurozone
Pricing (Generics)	65% of off-patent	65% of off-patent
	Re-pricing: • 65% of off-patent price • Reduction up to 10% every re-pricing	Re-pricing: Since, in the first application of the law, the generic is reduced by more than 10% of the price of the previous price list, generic prices are priced at 75% of the off-patent price
Re-pricing	2 times every year	1 time every year
Price list of new medicines	4 times every year (quarterly)	Pending MD

PRICE DEFINITIONS

Maximum Wholesaler Price: price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the wholesaler, which is calculated as a percentage on the maximum ex-factory price. Gross profit margin (mark-up) a) for all medicinal products reimbursed by social security funds is set as a percentage of 4.9% on the maximum net ex-factory price (up to €200) and 1,5% on the maximum net ex-factory price (>€200) b) for non-prescription medicinal products (OTC) as a percentage of 7.8% on the maximum net ex-factory price and c) for medicinal products that belong to par.2, art.2, L3816/2010 as a percentage of 2% on hospital price. The latter is called as Special Wholesaler Price.

Maximum Retail Price: price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy as set out in the respective ministerial decree and the applicable Value Added Tax (VAT 6.0%). In particular, for pharmacies the mark up is determined as follows: a) 35% on the wholesale price for non-prescription medicinal products (OTC) b) 35% on the wholesale price for non-reimbursed prescription products c) for reimbursed products (see Table 6) and for products with price > €3.000 is set a percentage of 2%.

Ex-factory price: price at which medicinal products are sold by the marketing authorization holders (MAHs) to wholesalers and is calculated based on the wholesaler price reduced a) for prescription medicinal products which are not reimbursed by the Social Insurance Funds by 5.4%, b) for prescription reimbursed medicinal products by the Social Insurance Funds with price up to 200 € by 4.67% and with a price exceeding € 200,01 by 1,48% and c) for non-prescription (OTC) medicinal products by 7.8%.

Maximum Hospital Price: price at which medicinal products are sold by the Marketing Authorization Holders to the State, State hospitals, Social Care Units, public law legal entities referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private clinics with over 60 beds and EOPYY pharmacies. The maximum hospital price shall be determined on the basis of the ex-factory price reduced by 8.74%.

Profit margins of wholesalers vary depending on the reimbursement status of each product that is, on whether the product belongs in the positive, negative, OTC list or if they fall under L.3816/2011 provisions and its relative wholesaler price. Also, pharmacists profit margins vary according to the wholesaler price of each product. For medicines belonging in the positive list (and therefore reimbursed by the social security funds) profit margins and the price structure are set as follows:

Table 5: Mark-up in the pharmaceutical supply chain

	Reimbursed Products up to 200€	Reimbursed Products > 200.01€	OTC	Negative list products
Wholesalers (over ex-factory)	4.9%	1.5%	7.8%	5.4%
Pharmacies	Table 6	Table 6	35%	35%

SOURCE: M.D. (3890/2.12.2016)

Table 6: Percentage of profit (mark-up) pharmacies

Wholesale price (€)	Percentage mark-up pharmacies
0-50	30.00%
50.01-100	20.00%
100.01-150	16.00%
150.01-200	14.00%
200.01-300	12.00%
300.01-400	10.00%
400.01-500	9.00%
500.01-600	8.00%
600.01-700	7.00%
700.01-800	6.50%
800.01-900	6.00%
900.01-1000	5.50%
1000.01-1250	5.00%
1250.01-1500	4.25%
1500.01-1750	3.75%
1750.01-2000	3.25%
2000.01-2250	3.00%
2250.01-2500	2.75%
2500.01-2750	2.50%
2750.01-3000	2.25%

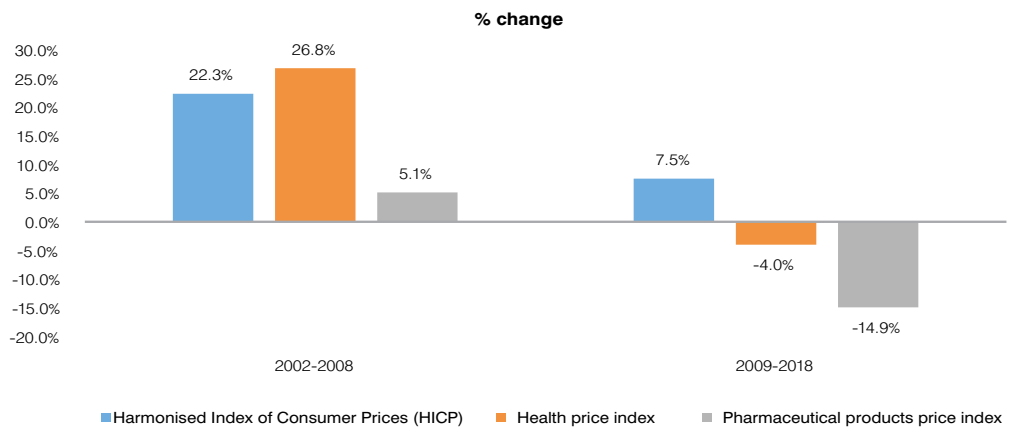
SOURCE: M.D. (3890/2.12.2016)

Mark-up margins mentioned above are the maximum margins allowed in the case of OTC for wholesalers and pharmacists, who may voluntarily provide these products in lower prices as long as it is recorded in the respective invoice.

Additionally, these margins are applied to all reimbursed products sold in private pharmacies including products of L.3816/2010 list. When the latter are directly sold by private pharmacies and the respective cost is not reimbursed by EOPYY or any other SSF, pharmacist margin is set based on the table above and for products with wholesaler price greater than €3.000 at 2%.

The period between 2002 and 2008, prices increased by 5.1% presenting the lowest increase between health index (+26.8%) and between categories of goods (22.3%), while between 2009 and 2018 the pharmaceutical price index decline with greater intensity (14.9% reduction).

Figure 51: Annual change (%) of HCIP by category (2015=100)



SOURCE: Eurostat. Harmonised Indices of Consumer Prices (HICP), 2019 data processing IOBE

5.8 HEALTH TECHNOLOGY ASSESSMENT (HTA)

The MAH (Holder of the Marketing Authorization) files an application to the HTA Committee for evaluation of the medicine, accompanied by a full dossier including all information and documentation. The Committee carries out a formal check of the dossier and informs the MAH of any deficiencies. If the dossier is incomplete, the MAH has 60 days to deposit the data otherwise required, the application will be rejected.

After the submission of the full dossier, a rapporteur and external evaluators are appointed who receive the dossier and draw up the relevant assessment reports. It is noted that the HTA Committee may, by unanimous and specifically reasoned decision, not appoint external evaluators or designate only one. The final proposal is then drafted, which is communicated to the members of the Evaluation Committee. Here is the evaluation of the suggestion. If the outcome of the evaluation is positive, the dossier shall be referred to the Negotiation Committee. The Negotiation Committee will hold a meeting with the MAH, assess the financial impact and suggest to the Evaluation Committee the compensation fee.

Then follows the opinion of the Negotiation Committee, which is forwarded to the Evaluation Committee and then to the Minister of Health. The decision of the Minister of Health shall be issued within 180 days of the filing of the application. If this deadline is over, the request is deemed to be rejected implied. Following the adoption of the decision of the Minister of Health, a summary of the opinions of the Evaluation Committee, which include at least their rationale, is published on the EOF's web site, after deletion of information regarding commercial confidentiality and personal data.

CHAPTER 6

STATE'S DEBT TOWARDS PHARMACEUTICAL COMPANIES

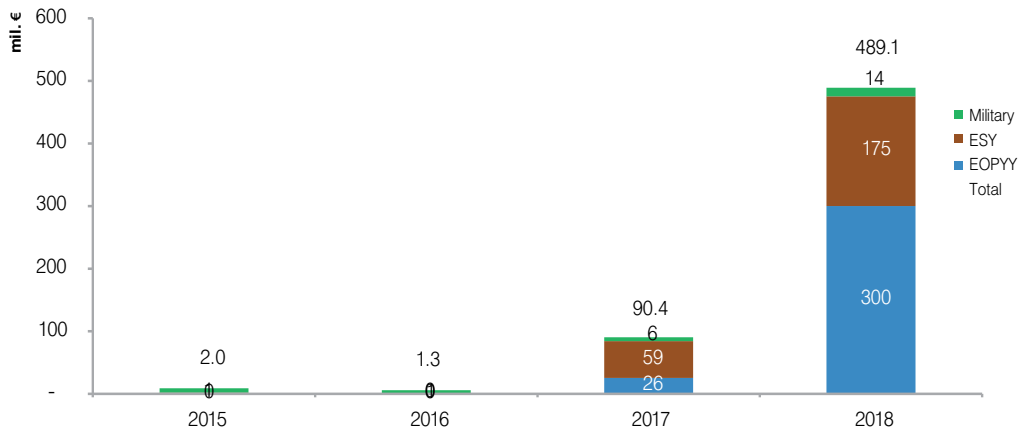
The Hellenic Association of Pharmaceutical Companies (SFEE) collects and records data related to State's debts of its member companies (on a voluntary basis). Below an overview of total receipts, sales invoices and debts until 31.10.2018 only for the pharmaceutical industry are presented.

Data for outstanding debts from ESY hospitals, EOPYY, and Military hospitals also constitute the largest part of health expenditure.

Specifically, findings show that:

The amount of government debts to SFEE member companies until 31.12.2018 amounted to €580.8 mil. The €489.1 mil. of which are invoices of 2018 and €90.4 mil. are from 2017. From the total €580.8 mil. €325.7 mil. are for EOPYY and the remaining €255.1 mil. For ESY and for military hospitals.

Figure 52: State debts evolution towards SfEE member companies' until per year (€ mil.)



SOURCE: SFEE

CHAPTER 7

APPENDIX

7.1 SYSTEM OF HEALTH ACCOUNTS (SHA)

In 2012, the Hellenic Statistical Authority (EL.STAT.) in collaboration with the Center for Health Services Management and Evaluation of the Nursing Department of the University of Athens and Dr. Markus Schneider (BASYS, Germany) published for the first time statistics on National Health Expenditures (both public and private) based on the System of Health Accounts (SHA) of the Organization for Economic Cooperation and Development (OECD). The Hellenic Statistical Authority (EL.STAT.) publishes every year statistical data for the Funding on Health Expenditures at national level based on the new System of Health Accounts manual SHA 2011 of the OECD, against SHA 1.0 that used for earlier data. Based on article 6 of the European Regulation (EU) 1338/2008 of the European parliament re matters of public health and the respective under voting Implementation Regulation and in cooperation from OECD & WHO the new compilation of SHA data was created. As such. EL.STAT was obliged to communicate SHA data to Eurostat and to International Organizations (OECD and World Health Organization) according to the new SHA 2011.

Transition table from SHA 1.0 to SHA 2011 codes

System of Health Accounts SHA 1.0	Funding Sectors (HF)	System of Health Accounts SHA 2011
HF.1.1	General Government (excl. Social Security Funds)	HF.1.1
HF.1.2	Social Security Funds (SSFs)	HF.1.2
HF.2.2	Private Voluntary Insurance Schemes	HF.2.1
HF.2.3	Private Households Out-of -pocket Expenditures	HF.3.1
HF.2.4	Non Profit Institutions Financing Schemes	HF.2.2
HF.2.5	Corporation Financing Schemes	HF.2.3
HF.3	Rest of the World	HF.4
HF.0	n.e.c	HF.0

System of Health Accounts SHA 1.0	Health care providers (HP)	System of Health Accounts SHA 2011
HP.1	Hospitals (public and private)	HP.1
HP.2	Residential. Long-term care facilities	HP.2
HP.3.1-3.4. HP.3.6	Providers of ambulatory health care	HP.3
HP.3.5. HP.3.9	Providers of ancillary services	HP.4
HP.4	Retailers and other providers of medical goods	HP.5
HP.5	Providers of preventive care	HP.6
HP.6	Providers of health care system administration and financing	HP.7
HP.7	Rest of Economy	HP.8
HP.9	Rest of the World	HP.9
HP.0	n.e.c	HP.0

The SHA is organised around a tri-axial system for the recording of health expenditure, defining:

- health care by function (HC)
- health care service provider industries (HP) and
- health care financing agencies (HF)

More specifically, on the basis of the aforementioned system (SHA 2011), for each expenditure category the following items are depicted:

- The funding agency - e.g. the Ministries (HF 1.1.), Social Security Funds (HF1.2), Households (HF 3.1). etc.
- The health care provider to which this expenditure is directed- e.g. General Hospitals (HP 1.1), Offices of physicians (HP 3.1), Offices of dentists (HP 3.2), etc.
- The health care function pertaining to each expenditure- e.g. Inpatient curative care (HC 1.1), Outpatient curative care (HC 1.3), etc.

The SHA 2011 has been adopted by most of OECD countries since all Member States of the EU are obliged to implement this system (pursuant to Community legislation) in order to transmit economic data for health care (from 2003 onwards) to OECD, Eurostat and WHO, through a common questionnaire jointly developed by the above three Organizations.

The SHA (for Greece) was developed in line with the "bottom-up" approach and following the funding agencies perspective. Health expenditure data were transmitted by the relevant Ministries (the Ministry of Health and Social Solidarity, the Ministry of Finance, the Ministry of National Defense, the Ministry of Culture, Education & Religious Affairs and the Ministry of Interior & Administrative Reconstruction), by the Social Security Funds (SSFs), by the Hellenic Association of Insurance Companies (EAEE), by Individual Non-Governmental Organizations, by the Church of Greece, by the Household Budget Survey (HBS) conducted by ELSTAT and the Managing Authority of the Ministry of Health.

Health expenditure, according to the new SHA methodology 2011 is comprised by the respective expenditure for:

Care Services. Rehabilitation

- HC.1 Hospitals (public and private)
- HC.2 Residential, Long-term care facilities
- HC.3 Providers of ambulatory health care

Ancillary Health Care Services

- HC.4 Providers of ancillary services (e.g. clinical diagnostic imaging and laboratory services, patient transport and emergency rescue services)

Products Supply for Outpatient Patients

- HC.5 Retailers and other providers of medical goods (pharmaceuticals, vision glasses, hearing aids, orthopedic belts and accessories)

Other Medical Products. Healthcare Management etc.

- HC.6 Preventive Care Services & Public Health
- HC.7 Healthcare Management & Social Security Funds
- HC.9 Non-specialized services by type

Funding of Health Expenditure: is defined as the Funding on Consumption Expenditure of resident units on health care goods and services. irrespective of where that consumption takes place (i.e. in the economic territory of the country or abroad), and irrespective of the funding agency (which may be in the economic territory of the country or abroad). Therefore. imports of health care goods and services must be included. while exports must be excluded.

Public or Private Funding of Expenditure is defined on the basis of the type (public or private) of the funding agency and on the basis of the type (public or private) of the Health Care Provider. For example, public funding of expenditure on hospitals does not mean the total expenditure of the public hospitals but the total amount of funding that both the public and the private hospitals get by the public funding agencies (Ministries. Social Security Funds).

Inpatient curative care services HC.1.1

- Under this category are included activities relating to inpatient services in either public, private, psychiatric and special treatment hospitals.

Day cases of curative care HC.1.2

- Under this category are classified all expenses relating to blood dialysis that are covered by any Social Security Fund (SSF).

Outpatient curative care HC.1.3

- This category reflects medical and paramedical examination for patients from outside the hospital. Moreover, services such as mobile care units. private clinics and diagnostic centers are also included under this category.

Pharmaceutical and other medical non-durables HC.5.1

- This category includes various pharmaceutical products such as medicines. sera. vaccines. bandages etc.

Therapeutic appliances and other medical durables HC.5.2

- This category includes medical supplies such as eyeglasses, hearing aids, orthopedic devices etc.

7.2 PHARMACEUTICAL EXPENDITURE-SALES

Data on "pharmaceutical expenditure" are often confused with data on "total pharmaceutical sales" released by the National Organization for Medicines (EOF).

EOF records sales of medicinal products from pharmaceutical companies to hospitals, wholesalers and pharmacies, on a monthly basis. On the other hand, according to the OECD's International Classification of Health Accounts, with which Greek statistics have been harmonized, pharmaceutical spending is the total expenditure for medicinal products prescribed for outpatient care (non-hospital treatment). Therefore, **pharmaceutical expenditure is only a fraction of total pharmaceutical sales.**

More precisely, pharmaceutical sales are composed of:

(a) Public pharmaceutical expenditure which is incurred by social insurance funds (partially returned to public funds, as VAT of 6% and mandatory discounts/ rebates/ clawback from pharmacists and pharmaceutical companies are included);

(b) Hospital sales from pharmaceutical products (invoiced at hospital price = ex-factory price minus 8.74% - rebates);

(c) Sales of pharmaceutical products that are re-exported (parallel exports);

(d) Sales of pharmaceutical products to Greek citizens or tourists at their own cost;

(e) Patient's copayment, which does not burden social security funds.

Regarding point (b), it should be noted that pharmaceutical sales to hospitals are included in hospital expenditure, so should be excluded from the analysis to avoid double-counting.

Regarding points (c) and (d), it should be noted that these sales are not part of public pharmaceutical expenditure; on the contrary, revenue to the government is generated, in the form of VAT, income tax, payroll tax, social security contributions, etc.

NOTES

NOTES

HELLENIC ASSOCIATION OF
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